

Instructions for Use 3 mL Sperm Purification Device

Device Components:

- SwimCount™ Harvester 3 mL Sperm Purification Device
- Instructions for Use
- Accessories: 1 x 3 mL Syringe and 2 x 1 mL Syringes

Equipment required, but not supplied:

- Sperm Preparation Medium
- 37°C or 98.6°F incubator

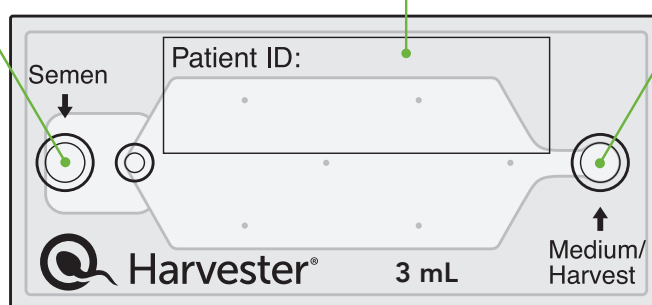
Semen Inlet Port for:

1. Adding semen sample

Patient ID Label Space

Medium Inlet/Harvest Outlet Port for:

1. Loading Sperm Preparation Medium
2. Harvesting purified spermatozoa



Important Information

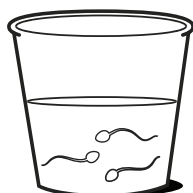
Please read detailed Instructions before use:

- Carefully adhere to the recommended volumes for each step
- Avoid both over- and/or underfilling of the device
- If spillage of sample occurs (resulting in less than a 3 mL sample) empty out the remaining sample in the collection, and start over filling the syringe with sample.
- Always load and aspirate the SwimCount™ 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
- The SwimCount™ Harvester comes sterile and a possible contamination from e.g. the work environment might decrease the efficiency of the SwimCount™ Harvester
- Practice universal precautions when handling human body fluids such as semen. Follow the guide lines described in the WHO laboratory manual for the examination and processing of human semen
- The device should be used only by properly trained operators
- Re-use of the device may lead to:
 - less efficient purification of the sample
 - contamination (e.g. two different semen samples)

1 Preparing the semen sample

Make sure that the semen sample is liquefied.

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



2 Aspirating the semen sample

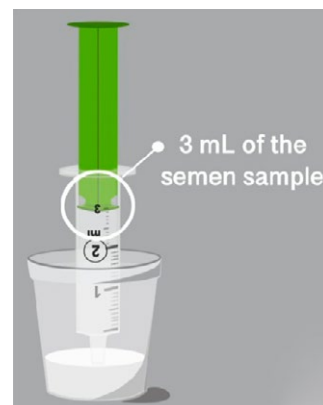
Before aspirating the semen sample, it must be homogeneous.

Aspirate 3 mL of the semen sample using the 3 mL syringe. Avoid any air bubbles.

If there is insufficient semen sample volume then add Sperm Preparation Medium* to bring the volume to 3 mL.

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

* Preparation of the Medium as informed by the manufacturers of the sperm preparation medium

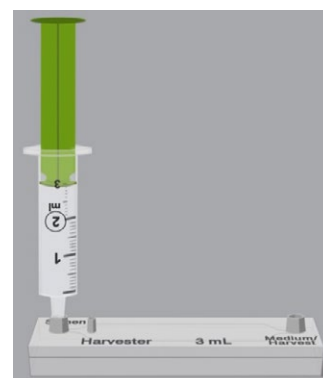


3 Inject the sample into the device

Place the 3 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.

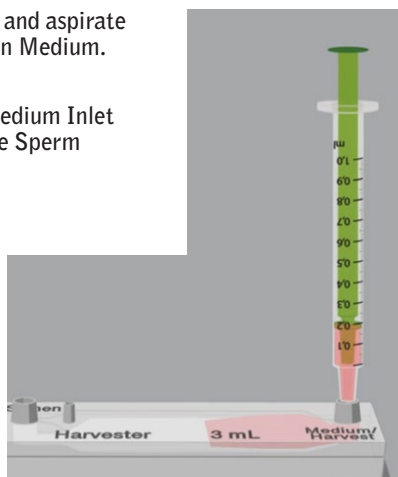
NOTE: Always handle the device on a flat horizontal surface (table).



4 Add the Sperm Preparation Medium

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

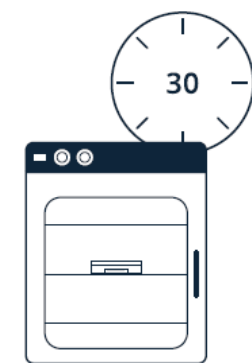
Place the syringe in the Medium Inlet Port and release slowly the Sperm Preparation Medium.



5 Incubation

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

Keep the device horizontally at all times.

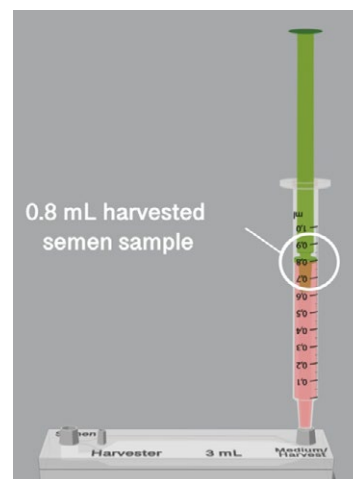


6 Harvest

Remove the device from the Incubator.

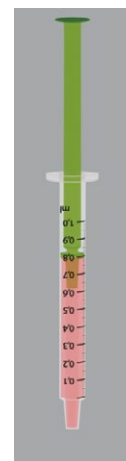
Use another 1 mL syringe and place it in the Harvest Outlet Port and aspirate 0.8 mL of the purified semen sample.*

*NOTE: Appr. 90-95% of the purified semen sample can be aspirated. Do not tilt the device in order to get the remaining 5-10% out.



7 The harvested sample is ready to be used

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



Device Description:

The SwimCount™ Harvester is a Sperm Purification Device. The device purifies the sperm sample by allowing only Progressive Motile Sperm Cells (PMSCs) to pass the device's membrane system. The SwimCount™ Harvester has a design/technology that 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 compartment 3 mL
- Medium/Swim-Up compartment 0.8 mL
- Micropore filter 10 µm.

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

Intended Purpose:

The intended purpose of the SwimCount™ Harvester is to purify semen samples and select for Progressive Motile Sperm Cells (PMSCs), and thereby be used in support of conception as part of Assisted Reproductive Technology (ART).

Sterilization:

The sterilization method used for the device is gamma radiation, at a dose level of 25kGy to 39kGy.

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 6°C - 37°C (42.8°F - 98.6°F).

Disposal:

Discard the used device and materials as medical waste.

Manufactured by:

MotilityCount ApS
Gl. Køge Landevej 57, 2.
DK-2500 Valby
Denmark
www.swimcountharvester.com

REF

INT1015.2

Contact:

If you have any questions, please contact us at: info@swimcount.com

In case any serious incident has occurred in relation to the device, it shall be reported to the manufacturer and the competent authority of the Member State.



Manufacturer



Expiration Date yyyy.mm



Lot Number



Catalogue Number



Sterilized Using Irradiation



Do Not Resterilize



Do Not Use if Package is Damaged



CE Mark Date of Issue: 2024-09-17

Instructions for Use in other languages:

For selected other languages please refer to the www.swimcountharvester.com site.



Fragile Item, Handle Carefully



Keep away from direct sunlight



Keep Dry



6°C - 37°C Storage Temperature Limits



Do Not Reuse



Consult Instruction For Use



Caution



Medical Device

Patents and Trademarks:

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

Patent: PCT W02014/177157