

NEW, better and more safe solution for Sperm Preparation for Assisted Reproductive Technology (ART)



Improving IVF, ICSI and IUI treatment results with the SwimCountTM Harvester

MDR CE Mark Approved

The SwimCount™ Harvester combines MotilityCount ApS' patented technology with intuitive design, taking sperm preparation into a very safe and user-friendly design.

The membrane technology of SwimCount™ Harvester is invented and patented by MotilityCount ApS in several countries around the World.

The technology is available both for Human Assisted Reproductive Technology (ART) and Animal Reproduction.

The SwimCount™ Harvester is a sperm purification device that mimics the natural selection of the best Progressive Motile Sperm Cells (PMSCs), with very few manipulation steps.

The PMSCs recovered show improved sperm quality parameters, especially an increased number of PMSCs with a very low DNA Fragmentation and a better Morphology.

The SwimCount™ Harvester sperm selection methodology reduces the number of steps necessary to perform the selection technique to the lowest level possible, decreasing the risk of human error, saving time and amount of cultivation media needed.



5 x SwimCount™ Harvester Devices in 5 different colors per Box

(both for the 1 mL and the 3 mL versions respectively)



Using five different colors makes it easy to differentiate between the semen samples similar to what is seen on colored straws for cryo preservation.



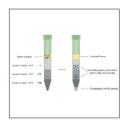


SwimCount™ Harvester Performance

1: Clinical results for SwimCount™ Harvester vs Density Gradient Centrifugation (DGC) in 111 patients (2021 performed by IVIRMA Global, Valencia – Published):

Sperm Parameters	SwimCount™ Harvester method compared with the DGC method*		
Total PMSCs (Millions)	Improved by 72%		
Live Sperm (%)	Improved by 11%		
Morphology (%)	Improved by 19%		
DNA Maturation (%)	Improved by 3%		
DNA Fragmentation (%)	Reduced by 64%		



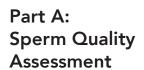


SwimCount™ Harvester

DGC

Microfluidics as a methodology for sperm selection. A prospective functional study

2: Clinical results SwimCount™ Harvester vs Swim-up in 50 patients (2023 performed by IVIRMA Global, Valencia – Unpublished interim analysis):







The
Clinical Study
has been finalised
in N=100 Patients
(by June 2024) and
will be published in a
Scientific Article by
IVIRMA Global
Valencia

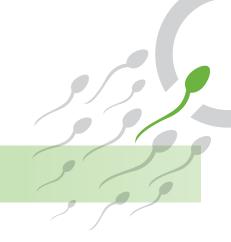
SwimCount[™] Harvester

Swim-up

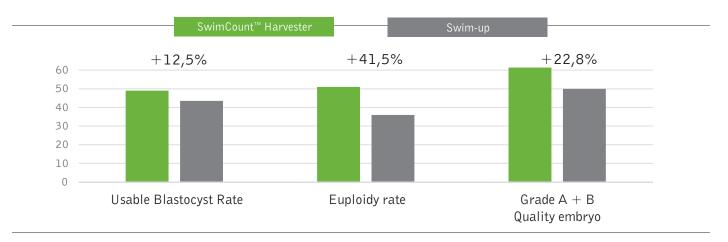


^{*} Source: Clinical Study performed by IVIRMA Global, Valencia Spain by Scientific Supervisor Marcos Meseguer and Andrology laboratory biologist and Predoctoral Researcher Fernando Meseguer

F Meseguer Estornell, R Rivera Egea, L Bori Arnal, M.Á Valera Cerdá, C Giménez Rodríguez, A Garg and M Meseguer Escrivá Human Reproduction, Volume 37, Issue Supplement_1, July 2022, deac107.026, https://doi.org/10.1093/humrep/deac107.026



Part B: Embryo Quality Assessment



Effect of sperm selection method in elderly patients							
Woman Age	Method	Fertilization Rate (%)	Blastocyst Rate (%)	Usable Blastocyst Rate (%)	Euploidy Rate (%)		
≥ 40 years (N= 20)	SwimCount™ Harvester	72,52	62,12	57,58	30,43		
	Swim-up	73,11	61,76	55,88	8,70		
≥ 42 years (N= 12)	SwimCount™ Harvester	77,55	60,53	60,53	10,00		
	Swim-up	73,08	55,26	50,00	0,00		

Effect of sperm selection method in patients with high DNA Fragmentation							
SDF level	Method	Fertilization Rate (%)	Blastocyst Rate (%)	Usable Blastocyst Rate (%)	Euploidy Rate (%)		
SDF ≥ 15% (N= 13)	SwimCount™ Harvester	76,47	71,15	51,92	50,00		
	Swim-up	78,12	56,00	26,00	33,33		
SDF ≥ 20% (N= 8)	SwimCount™ Harvester	70,00	71,42	50,00	25,00		
	Swim-up	74,28	57,69	19,23	No data		





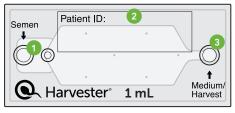
Conclusion

The SwimCountTM Harvester is presented as a novel sperm selection methodology to be taken into account in the coming years. The observations provided in the interim analysis show trends of increase in the rates of useful blastocyst and euploidy as well as improvement of embryo quality, that will be confirmed or refuted at the end of the blinded study, being the continuity of the same. Preliminarily, the significant improvement in sperm quality stands out. Likewise, the number of steps necessary to perform the selection technique are reduced to the lowest level possible, decreasing the risk of human error, saving time and amount of cultivation media needed.



Two different device formats with different functions

The 1 mL device is for IVF and ICSI Treatment





The 3 mL device is for IUI Treatment Semen Patient ID: 2 Harvester 3 mL Medium/ Harvest

- 3 Medium Inlet/Harvest Outlet Port for:
 1. Loading Sperm Preparation Medium
 - 2. Harvesting purified spermatozoa

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

Semen Inlet Port for:

1. Adding semen sample

3 mL 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

Quick Guide Detailed Instructions for Use are included in the package



1: Preparing the semen sample Make sure that the semen sample is liquefied.

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



5: Incubation

Incubate the device for 30 Min at 37°C or 98.6°F. Keep the SwimCount™ Harvester device horizontally at all times



2: Aspirating sample

Before aspirating the semen sample, it must be homogeneous. Aspirate 1 or 3 mL of semen sample using one of the included syringes. Avoid any airbubles. If there is insuffient semen sample volume then add Sperm Preparation Medium* to bring the volume to 1 or 3 mL (depending on device size). NOTE: If using a frozen semen sample then follow the instructions from the Sperm Bank for thawing.



6: Harvest

Remove the SwimCount™ Harvester device from the Incubator. Use a new syringe and place it in the Harvest Outlet Port and aspirate all the Sperm Preparation Medium containing the purified sperm 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.



3: Inject the sample into the device

Place the 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 SwimCount™ Harvester device.

NOTE: Always handle the device on a flat horizontal surface (table). It is important to note, that the SwimCount™ Harvester should not be overloaded. Use 1 mL or 3 mL semen, only.



7: Sample is ready to be used

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



4: Add the Sperm Preparation Medium

Use a new syringe and aspirate 0.8 mL Sperm Preparation Medium. Avoid any airbubles. Place the syringe in the Medium Inlet Port and release slowly the Sperm Preparation Medium. It is important to note, that the SwimCount™ Harvester device should not be overloaded. Load 0,8 mL Sperm Preparation Medium, only.

 $\mbox{\ensuremath{^{\ast}}}$ Preparation of the Medium as informed by the manufactures of the sperm preparation medium



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