

SEAFORIA AT HOME Kit a conception assistance device for home use

INSTRUCTION FOR USE

1. Indications for Use – Seaforia AT HOME Kit

The *Seaforia AT HOME* is a conception assistance Kit for home use, intended to aid in the process of becoming pregnant. The *Seaforia AT HOME* Kit contains an optimal semen container, providing environment for best sperm cells to swim in a natural way, and be collected, for further possible Artificial Insemination – (AI). Progressively motile and normal morphology sperm cells are the preferable prerequisite for fertilization and embryo development. However, using the *Seaforia AT HOME* Kit, is not a guarantee for the occurrence of ovum fertilization and for further normal development of the embryo since additional factors contribute to a successful conception.

The *Seaforia AT HOME* includes a variety of components for sperm assistance which may further be used in the process of Artificial insemination (AI).

The Kit enables assisting sperm cells swim in a natural way, same as happening during normal intercourse insemination.

The key benefits of the *Seaforia™ AT HOME* Kit:

- Unique, simple and easy to operate for home use.
- Allows a natural assistance process for sperm cells with minimal handling, at home.

The main risks in the *Seaforia™ AT HOME*:

Following the instructions will provide best results. • Not following the instructions, may result in partial process and using native row semen, without the benefits of the *Seaforia AT HOME* assistance Kit. • The *Seaforia AT HOME* Kit, a conception assistance device for home use, is intended to aid in the process of becoming pregnant, and is intended to assist conception. • The *Seaforia AT HOME* Kit includes a variety of components for sperm assistance which may further be used in the process of Artificial insemination (AI). • The *Seaforia AT HOME*, your conception assistance Kit, provides new possibilities for Artificial insemination (AI), comfortably at your home, during the ovulatory phase of the menstrual cycle.

- Carefully read the Instruction for use, through all stages. In case you need additional info please contact your Physician.

IMPORTANT!

The *Seaforia AT HOME*, your conception assistance Kit, is not intended as a contraceptive device. • The *Seaforia* semen container is indicated for holding sperm for periods not exceeding one (1) hour. • Do not use this product if it is medically unsafe for you to engage in sexual intercourse or become pregnant, or using a UN known source of semen. • Do not use The *Seaforia AT HOME* if you or your insemination partner have been diagnosed with any of the following conditions: no sperm in semen (azoospermia), blocked fallopian tubes, known STD's (including active herpes, hepatitis), HIV, loss of fallopian tubes due to surgeries, or have had a hysterectomy. If lesions, open sores, viral warts, or other abnormalities are noticeable on either partner, avoid sexual intercourse and consult your Physician. • *Seaforia AT HOME* Kit is intended as an aid to conception and does not guarantee pregnancy. • To avoid a choking hazard, keep all of The *Seaforia AT HOME* components out of reach of children. • The *Seaforia AT HOME*, your conception assistance Kit, is for single use only!!!


In case package is damaged, do not use, please contact manufacturer!

Semen collection cup is needed to collect the semen. • 0.8 ml Medium is needed per each semen container, it is recommended to purchase small volume units of medium for each time you use the Kit, not for re use once opened. • Do not start using the *Seaforia AT HOME* Kit if you do not have such a compatible medium, and a semen collection cup. • If conception has not been resulted following 6 months of trying to become pregnant, consult your physician

- * Using the *Seaforia™ AT HOME* Kit: please make yourself available for a relaxed and private time.

2. Exploring the *Seaforia AT HOME*

The *Seaforia™ AT HOME* Kit CAT number 10257 content:

1	Packaging	
2	2X semen container of 1 ml & 6 tips	
3	Pipette x1	
4	3ml syringe x1	
5	3 ml syringe X1	
6	Stativ X2	
7	1ml syringe x1	
8	Vial x1	
9	IFU Instructions for use X1	

List of all *Seaforia™ AT HOME* Kit and devices

Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use
CAT10257	<i>Seaforia AT HOME</i> KIT	<i>Seaforia AT HOME</i> Kit a conception assistance device for home use	The <i>Seaforia AT HOME</i> Kit, a conception assistance device for home use is intended to aid in the process of becoming pregnant. The <i>Seaforia AT HOME</i> includes a variety of components for sperm assistance which may further be used in the process of Artificial Insemination (AI). contains <i>Seaforia</i> SEMEN CONTAINER XX ml +tips, SELECTED FROM GROUP OF DEVICES: (CAT 10266,10267, 10268, 10269,10270,10271) + STATIV,3 syringes, pipette & vial

3. How should you use the *Seaforia™ AT HOME* KIT?

Please make sure, that semen collection cup and Medium for the process are available!



1) Semen collection – Instruct your insemination partner

Instruct your partner to collect his ejaculated semen sample into a, clean, wide-mouthed Semen collection cap.

2) Allow semen sample to liquefy following ejaculation prior to beginning using the Kit.

The assistance process using the *Seaforia AT HOME* Kit should start within 45-60 minutes from ejaculation.

- Wash hands thoroughly with soap and water.

3) Open the *Seaforia™ AT HOME* kit package (1).

4) Take the Pipette (3) for semen sample homogenizing.

Squeeze the pipette outside the semen collection cap, then insert its edge into the semen. Pump it gently while drawing the semen into the pipette. Repeat the process 10 times carefully. Avoid pumping air bubbles into the semen and pipette! The semen viscosity should be now in a watery composition and, not viscous.

* If the semen sample is still viscous, repeat the process gently for additional 20 times. Check again for viscosity and repeat if necessary. Avoid creating bubbles or foam.

5) Use the 3ml (4) syringe for drawing the semen from the Semen collection cup and read the total sample volume.

In order to measure the correct volume, read the volume as measured at the syringe's piston. There is no need to insert the sample back into the container. The best practice recommended is to perform the procedure utilizing the whole semen volume divided into complete portions. • Note: *Seaforia AT HOME* semen container (2) is designed for exact portions of 1 ml semen, as marked on the semen container.

Loading the Semen.

6) Place the *Seaforia™ AT HOME* container (2) in the cavity of the Stativ (6).

Confirm that the *Seaforia AT HOME* container is sitting properly on the stativ, which is further aligned properly on a flat leveled surface such as a table.

7) Connect the tips (2) supplied with the container, to all 3 syringes (7, 4, 5) to the Luer tip (2).

8) Insert the 3ml (4) syringe containing the semen into the central opening of the *Seaforia™ AT HOME* container(2), marked .

Gently and slowly deposit the correct semen volume according to the container. Do not force the Tip. Loading the semen should take about 20 seconds, to avoid bubbles. As required, repeat this step for the remaining semen portions using additional *Seaforia AT HOME* container, selected for the process.

Loading the Medium

9) Open the medium bottle as instructed by the medium manufacturer.

Draw 0.8ml medium into the second 3 ml syringe (5). In order to measure the correct volume, read the volume as measured at the syringe's piston.

10) Insert the syringe's tip to the [M] peripheral opening of the *Seaforia™ AT HOME* container (2) and gently and slowly deposit the medium into the container.

Do not force the Tip. Loading the medium should take about 20 seconds. • In case there is more than one container planned for the procedure Repeat loading the medium to additional *Seaforia AT HOME* container selected for the process.

11) Allow time to pass at room temperature, 30 - 45 minutes, not exceeding 60 minutes!

Drawing out the Sperm

12) Take the 1ml (7) syringe connected to a tip.

Insert the 1ml syringe (7) into the peripheral opening [M] of the *Seaforia AT HOME* container (2) until it reaches the bottom of the container compartment.

Do not force the syringe further. Gently draw the medium with sperm (very slowly to improve results). Make sure to draw all medium volume until bubbles appear.

In case you used more than one container for the procedure, please open the vial (8) and slowly, deposit the syringe's content into the vial (8). Close the lid of the vial (8).

13) Repeat step#12 for all remaining containers (2).

















14) Now the content of the vial is ready for further use in the process of Artificial insemination (AI), using an approved device or Physician or nurse's support.

15. Dispose all packages, containers and components of *Seaforia™ AT HOME* Kit, Do not re use!

4. Appendix

Maintenance: No. Single use, low bio-burden,

Glossary Symbols to convey information essential for proper use:

Symbol	Meaning	Symbol	Meaning
	Do not reuse		Temperature limitation
	Consult operating instruction		Use by
	Keep away from sunlight		Date of manufacture
	Keep dry		Batch code
	Legal manufacturer		Attention! Read Instructions for Use
	EU Authorized Representative		Medium insertion and drawing out sperm opening
	Do not use if package is damaged		Semen insertion central opening
	CE MARK		Artificial Insemination

Seaforia AT HOME Kit and devices a conception assistance Kit for home use

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