

Material included in the kit:

- 1 x Vial with 2 ml of GM501 SpermAir Medium
- 2 x 2 ml-Syringes
- 1 x Short cannula
- 2 x Long cannulas
- 1 x Ampulla rack
- 1 x Insemination Catheter
- 1 x Instructions for use

Material not included in the kit:

- Incubator (no CO₂)/ warming cabinet

Product code:

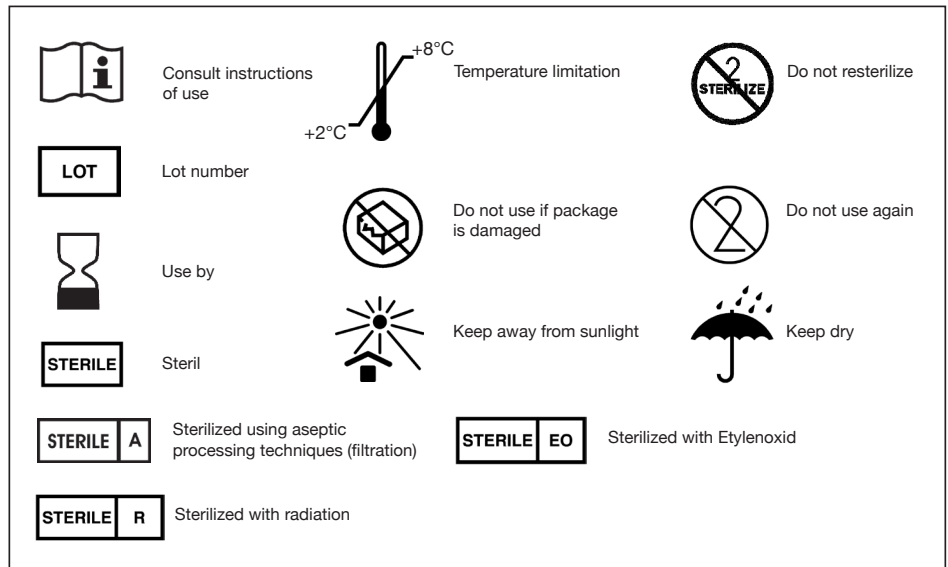
1 x Insemination Kit with
Inseminationskatheter **Standard**

- 4SA-KIT-002

1 x Insemination Kit with

Inseminationskatheter **Memo**

- 4SA-KIT-002-memo



Intended use/Intended users:

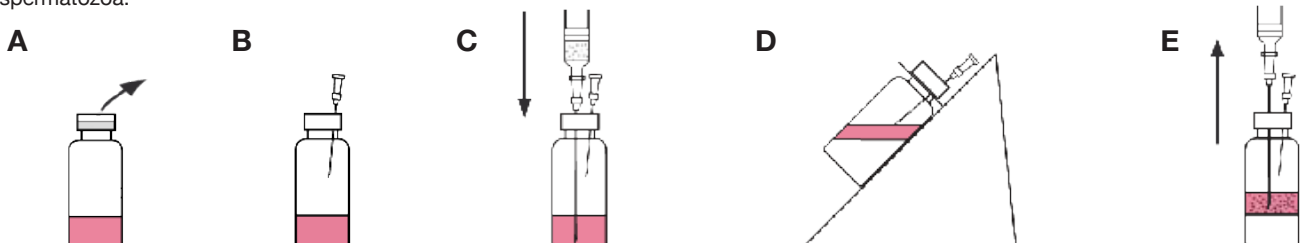
- The Insemination Kit is a complete system for the simple and safe preparation and processing of human spermatozoa out of the ejaculate for homologous and heterologous intrauterine inseminations (IUI).
- The Insemination Kit uses the self motility of the male germ cells to isolate motile spermatozoa in high concentrations. We recommend the use if the ejaculate is normozoospermic and slightly oligo- and/ or asthenozoospermic.
- The intended users are IVF professionals (lab technicians, embryologists or medical doctors).

Instructions for use:

1. Warm up GM501 SpermAir vial to 37°C.
2. Remove metal cap from the stopper and disinfect the stopper's surface with isopropylalcohol (70 %). (see picture A)
3. Insert the enclosed short cannula through the stopper. It serves as pressure balance valve. (see picture B)
4. Aspirate liquefied, analysed ejaculate into an enclosed 2 ml-syringe and attach a long cannula.
5. Hold the syringe with its tip upwards to collect air in the upper part of the syringe and press it out.
6. Now insert the syringe's cannula (tip downwards) through the vial's stopper until the tip attaches the bottom of the vial. (see picture C)
7. Now release the ejaculate slowly and carefully by pressing it out of the syringe and let it suspend under the preparation medium without mixing the two liquids.
8. After deflation remove the syringe with the cannula carefully while leading the tip along the inner wall of the vial. Discard the syringe and the cannula.
9. Now carefully place the vial's neck into the rack's fork and store the vial at 37°C in a incubator (no CO₂)/ warming cabinet for least 45 minute and not longer than 3 hours. (see picture D)
10. After the time carefully take the vial out and turn it upright. Attach a fresh long cannula on the tip of a fresh 2 ml-syringe and insert it again through the disinfected stopper.
11. Aspirate 0.5 to 1.0 ml of the upper media layer and remove the syringe with the cannula. (see picture E) The syringe now contains the SpermAir-fraction with the isolated motile sperms. Until the insemination procedure place the syringe with the cannula with the attached protection cap of the cannula in a incubator (no CO₂)/ warming cabinet by 37°C.
12. To inseminate remove the cannula from the syringe and attach the enclosed IUI-catheter at the tip of the syringe. Previous to the filling with the suspension 1 ml air is being aspirated into the syringe, so it is assured that the total probe will be spend during insemination into the cavum uteri. (Dead air volume of the catheter 1,3 mm³).
13. The position assistance is adjusted corresponding to the anatomical proportions determined before.
14. The catheter is inserted until the position assistance is being on the outer uterine orifice.
15. As soon as the requested position has been reached, the catheter will be turned, so that the marks on the grip are lying visible on top. In this way both of the lateral openings at the very end of the catheter are lined up towards the applicators orifice.
16. The suspension with the spermatozoa is injected slowly into the cave uteri.
17. Finally the catheter is slowly being extracted out of the uterus.

Advice:

- If the sperm is not liquefied sufficiently 30 minutes after the ejaculation, liquefy it by aspirating it into a sterile disposable syringe (2 or 5 ml) and flushing it out several times. Before doing this, let disturbing rude particles sediment and do not aspirate them into the syringe
- It is recommended to analyse the sperm concentration prior to the insemination. For the insemination at least 2 million grade A spermatozoa should be present. An insemination with lower than 0,5 M/ml is not recommended. If performed optimally, the sperm suspension contains no or just very few im-mo-tile spermatozoa.



GM501 SpermAir Medium (included in the Insemination Kit) C € 0344**Composition:**

- NaCl, KCl, KH_2PO_4 , $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$, NaHCO_3 , $\text{CaCl}_2 \cdot 2\text{H}_2\text{O}$, D(+)-Glucose anhydrous, Na-Lactate (50 % solution), Na-Pyruvate, EDTA, Alanyl-Glutamine, 21 mM HEPES, water, non-essential and essential Amino Acids, human serum albumin (5.00 g/Liter), Gentamicin (10 mg/Liter), Phenolred.

Product specifications and quality control:

- All raw materials are of highest available purity (European Pharmacopoeia and/or USP standard) if applicable.
- A certificate of analysis is available for each batch upon request from our website with respective lot number.
- The MSDS for GM501 SpermAir is available upon request and can also be downloaded from our website.
- GM501 SpermAir is manufactured according to the following specifications:

pH (at 37°C)	7.20-7.50
Osmolality (mOsm/kg)	270-290
Sterility	sterile - $\text{SAL}10^{-3}$ (Sterility Assurance Level)
Endotoxin (EU/ml)	< 0.25
MEA (Blastocysts in %; after 5 days of culture in the product covered by mineral oil, starting from zygote stage)	≥ 80

Precautions and warnings:

- GM501 SpermAir contains the antibiotic Gentamicin Sulfate. Appropriate precautions should be taken to ensure that the patient is not sensitized to this antibiotic.
- Standard measures to prevent infections resulting from the use of medicinal products prepared from human blood or plasma include selection of donors, screening of individual donations and plasma pools for specific markers of infection and the inclusion of effective manufacturing steps for the inactivation/removal of viruses. Despite this, when medicinal products prepared from human blood or plasma are administered, the possibility of transmitting infective agents cannot totally be excluded. This also applies to unknown or emerging viruses and other pathogens. There are no reports of proven virus transmissions with albumin, manufactured to European Pharmacopoeia specifications by established processes.
- Therefore, handle all specimens as if capable of transmitting HIV or hepatitis. Always wear protective clothing when handling specimens.
- Always work under strict hygienic conditions (ISO 5 environment, e.g. LAF-bench) to avoid possible contamination, even when GM501 SpermAir Medium contains Gentamicin.
- Only for the intended use.
- The user facility of this device is responsible for maintaining traceability of the product and must comply with national regulations regarding traceability, where applicable.

Pre-use checks:

- Do not use the product if bottle, seal of the container or package is opened or defect when the product is delivered.
- Do not use the product if it becomes discoloured, cloudy or shows any evidence of microbial contamination.

Disposal:

- The products must be disposed like potential contaminated, specific to each country.

Storage instructions and stability:

- The shelf life is 6 months from time of manufacture.
- Store between 2-8°C.
- Do not freeze before use.
- Keep away from (sun) light.
- The product can be used safely up to 7 days after opening, when sterile conditions are maintained and the products are stored at 2-8°C.
- Stable after transport (max. 5 days) at elevated temperature ($\leq 37^\circ\text{C}$).
- Content cannot be re-sterilized after opening.
- Do not use after expiry date.

For technical support:

GYNEMED GmbH & Co. KG,

Wagrienring 24b, 23730 Sierksdorf - Germany

Phone: +49 (0) 4561 5 13 25-00 - Fax: +49 (0) 4561 5 13 25-19

Email: info@gynemed.de - <http://www.gynemed.de>