

SpermSlow™

Product No.:

1094

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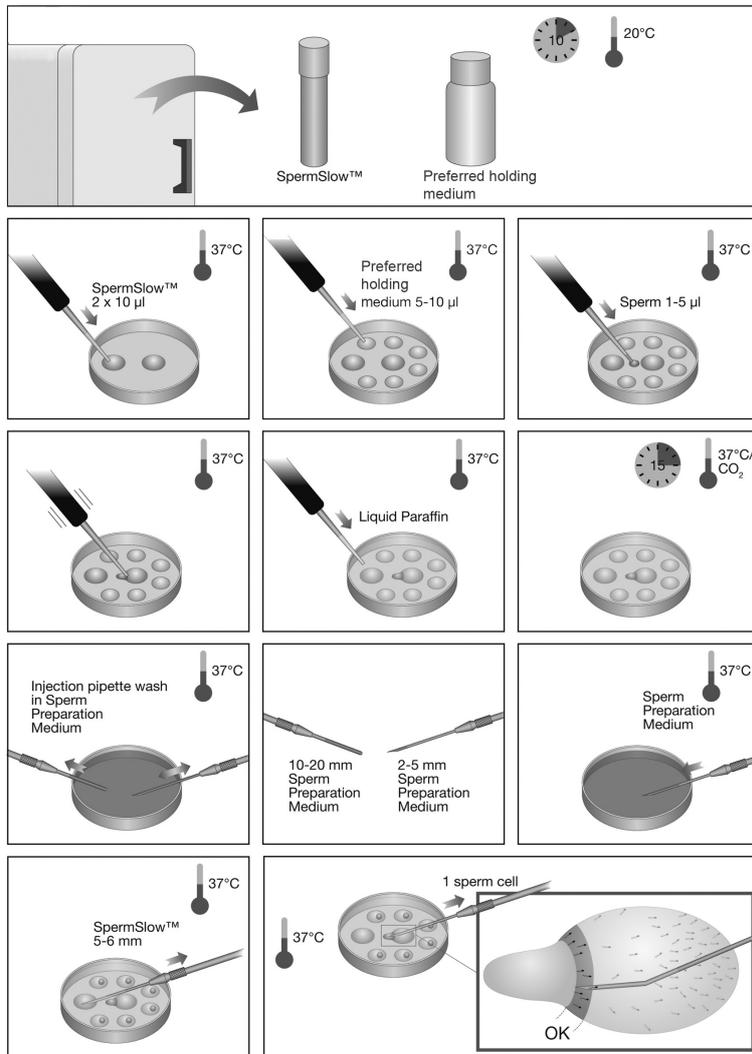
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SpermSlow™

Intended use

SpermSlow™ is used to slow down the movement and to select the most viable sperm as required for intracytoplasmic sperm injection (ICSI).

Composition

Hyaluronate
HSA (Human serum albumin)
Recombinant human insulin
Glucose and derived metabolites
Physiological salts
Nucleotides
Amino acids
Vitamins
Sodium bicarbonate
Gentamicin sulphate 10µg/mL

Quality control testing

Sterility tested (Ph.Eur., USP)
Endotoxin tested ≤ 0.1 EU/mL (Ph.Eur., USP)
Not Mouse Embryo Assay (MEA) Tested
Sperm Survival tested
Performance tested

Note: The results of each batch are stated on a Certificate of Analysis, which is available on www.origio.com.

Storage instructions and stability

Store in original container at 2-8°C, protected from light.
Do not freeze.
Discard excess (unused) media following warming.
The product is provided in vials intended for single use.

When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.

Precautions and warnings

Do not use the product if:

1. Product packaging appears damaged or if the seal is broken.
2. Expiry date has been exceeded.

Caution: All blood products should be treated as potentially infectious. Source material used to manufacture this product were tested and found non-reactive for HbsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore source material have been tested for parvovirus B19 and found to be non-elevated. No known test methods can offer assurances that products derived from human blood will not transmit infectious agents.

Caution: U.S. federal law restricts this device to sale by or on the order of a physician (Rx only).

Note: SpermSlow™ allows for an active selection of mature spermatozoa when performing ICSI. SpermSlow™ is not a general immobilising agent (such as PVP); therefore it has quite different characteristics. The active ingredient in SpermSlow™ is hyaluronate (HA), which is naturally occurring in the human body. HA forms a 'grid' that mature spermatozoa will bind to. Therefore, only mature spermatozoa are slowed by SpermSlow™, while immature spermatozoa will move freely.

In order to get the full benefit from SpermSlow™ please follow the instructions carefully.

Instructions for use

1. Remove SpermSlow™ and the preferred holding medium from storage at 2-8°C and leave at room temperature for 10 minutes.
2. Pipette 2x 10 µL of SpermSlow™ onto the bottom of the ICSI dish, which should be kept at 37°C during the whole procedure (1 drop in centre, 1 drop at the rim of the dish).
3. Depending on the number of oocytes used in the ICSI procedure, pipette a corresponding number of 5-10 µL droplets of the preferred holding medium.
4. Introduce a small amount e.g. 1-5 µL of prepared and washed sperm close to the SpermSlow™ drop in the centre of the ICSI dish.
5. Use the pipette tip to create a junction between the sperm droplet and the SpermSlow™ drop in the centre.
6. Immediately cover the ICSI dish with pre-equilibrated Liquid Paraffin and place it in a 5-6% CO₂ incubator at 37°C for 15 minutes prior to use.
7. Wash/rinse the injection pipette in pre-equilibrated Sperm Preparation Medium. Aspirate 10-20 mm into the holding pipette and 2-5 mm into the injection pipette.
8. After 1 minute expel the Sperm Preparation Medium from the injection pipette into the dish with the Sperm

Preparation Medium. The injection pipette is now coated to avoid sperm and SpermSlow™ adhering to the needle.

9. Place an oocyte in each droplet of preferred holding medium.
10. Aspirate 5-6 mm SpermSlow™ from the SpermSlow™ drop at the rim of the ICSI dish.
11. Carefully select a mature spermatozoon from near the junction between the sperm droplet and the SpermSlow™ drop. Mature spermatozoa will be bound to the Hyaluronate in SpermSlow™. Therefore, look for the spermatozoon with the best morphology, and which has a moving tail but no forward motion (i.e. is 'moving in place').
Spermatozoa moving freely in the SpermSlow™ drop are immature spermatozoa and should not be selected.