

# SpermSlow™

## Product No.:

1094

## Customer Service:

E-mail: Sales@coopersurgical.com



### ORIGIO a/s

Knardrupvej 2, 2760 Måløv, Denmark

www.fertility.coopersurgical.com

Tel: +45 46 79 02 00

Sponsor: ORIGIO AUSTRALASIA Pty Ltd

| Level 35 One International Towers, 100

Barangaroo Avenue, NSW 2000 | Sydney,

Australia

# origio

a CooperSurgical Company

## Explanation of Symbols (in random order)



Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure



Do not use if package is damaged



Discard excess (unused) media following warming



Indicates the medical device manufacturer



Indicates the manufacturer's batch code so that the batch or lot can be identified



Indicates the date after which the medical device is not to be used



Indicates the manufacturer's catalogue number so that the medical device can be identified



Indicates a medical device that has been manufactured using accepted aseptic techniques



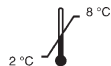
Indicates a medical device that needs protection from light sources



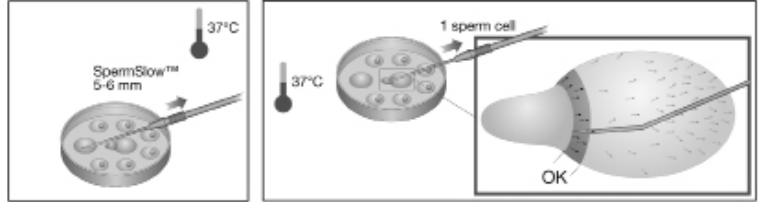
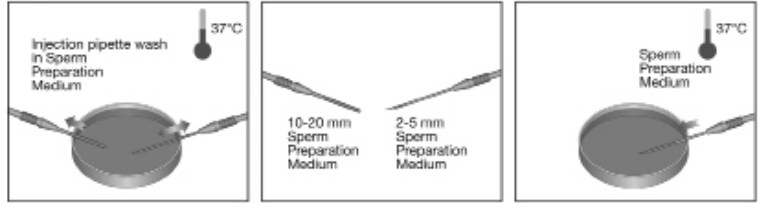
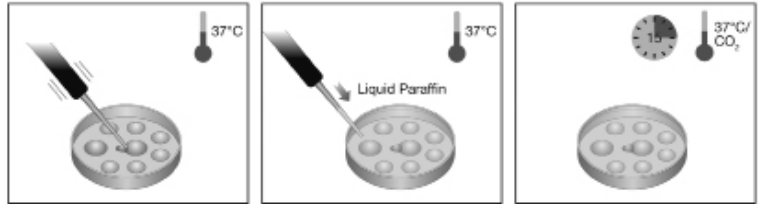
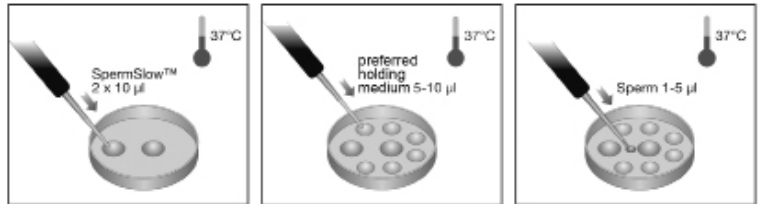
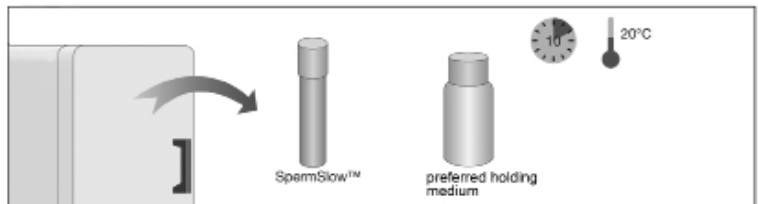
Indicates the need for the user to consult the instructions for use



Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions



Indicates the temperature limits to which the medical device can be safely exposed



# SpermSlow™

## Intended use

SpermSlow™ is for slowing down the movement of the sperm to allow for the selection of the most mature, viable spermatozoa for intracytoplasmic sperm injection (ICSI).

This product is for ART treatment, whether the cause of infertility is male or female. The product should only be used by professionals trained in ART treatment.

## Composition

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

## Quality control testing

Sterility tested (Ph.Eur., USP)  
Endotoxin tested ≤ 0.1 EU/ml (Ph.Eur., USP)  
Sperm survival tested ≥ 80%  
Performance tested  
Viscosity tested

**Note:** The results of each batch are stated on a Certificate of Analysis, which is available on [www.fertility.coopersurgical.com](http://www.fertility.coopersurgical.com)

## Storage instructions and stability

The products are aseptically processed and supplied sterile.

Store in original container at 2-8°C, protected from light.  
When stored as directed by the manufacturer the product is stable until the expiry date shown on the vial label.  
Do not freeze.  
The product is provided in vials intended for single use.  
Excess (unused) media should be discarded.

## 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 from which this product was derived was found negative when tested for antibodies to HIV, HCV, and non-reactive for HBsAg, HCV RNA and HIV-1 RNA. No known test methods can offer assurance that products derived from human blood will not transmit infectious agents.

The potential risk of reproductive or developmental toxicity due to the use of ART media has not been determined and is still unknown.

## Notes:

Dispose of the device in accordance with local regulations for disposal of medical devices.

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 holding medium from storage at 2-8°C and leave at room temperature for 10 minutes.
2. Pre-equilibrate the holding medium and the ICSI dish at 37°C for a minimum of 30 minutes
3. Pipette 2x10µl 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).
4. Depending on the number of oocytes used in the ICSI procedure, pipette a corresponding number of 5-10µl droplets of holding medium.
5. Introduce a small amount e.g. 1-5µl of prepared and washed sperm close to the SpermSlow™ drop in the centre of the ICSI dish.
6. Use the pipette tip to create a junction between the sperm droplet and the SpermSlow™ drop in the centre.
7. Immediately cover the ICSI dish with pre-

equilibrated Liquid Paraffin and place it in a CO<sub>2</sub> incubator at 37°C for 15 minutes prior to use.

8. 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
9. 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.
10. Place an oocyte in each droplet of holding medium.
11. Aspirate 5-6 mm SpermSlow™ from the SpermSlow™ drop at the rim of the ICSI dish.
12. 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.*