

SpermSlow™

Product No.:

1094

Customer Service:

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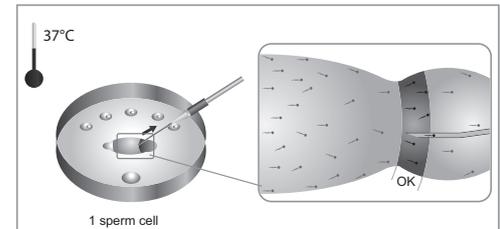
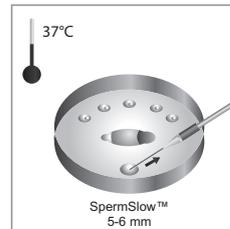
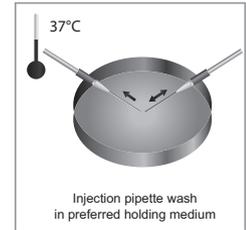
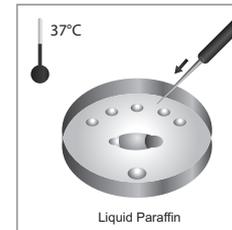
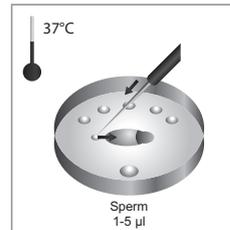
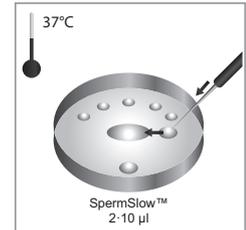
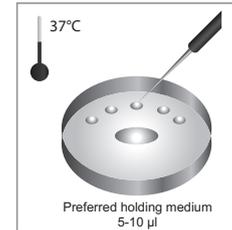
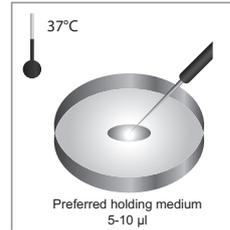
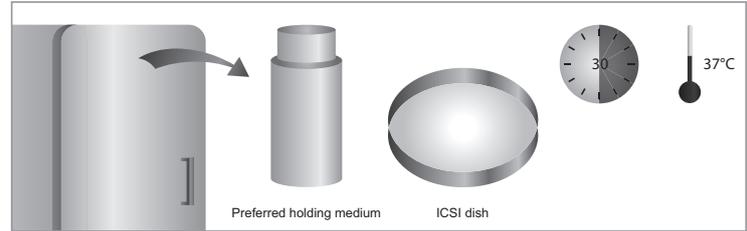
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a CooperSurgical Company



SpermSlow™

Intended use

SpermSlow™ is used to slow down the movement of sperm to allow for the selection of the most mature, viable sperm for IntraCyttoplasmic Sperm Injection (ICSI).

Composition

Hyaluronate
Human serum albumin (HSA)
Recombinant human insulin
Glucose and derived metabolites
Physiological salts
Nucleotides
Amino acids
Vitamins
Sodium bicarbonate
Gentamicin sulphate 10 µg/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 at www.fertility.coopersurgical.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 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. The source material used to manufacture this product was tested and found non-reactive for HBsAg and negative for Anti-HIV-1/-2, HIV-1, HBV, and HCV. Furthermore, source material has 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 three-dimensional net to which mature spermatozoa expressing HA receptors will bind. Therefore, only mature spermatozoa are slowed by SpermSlow™, while immature spermatozoa or those not expressing HA receptors will move more freely.

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

Instructions for use

1. Ensure Liquid Paraffin is pre-equilibrated according to standard protocol and warm the preferred holding medium (e.g. Flushing Medium, QA with HEPES) and ICSI dish to 37°C for a minimum of 30 minutes.
2. Dispense an elongated (bridging) drop (5-10 µL) of holding medium into the ICSI dish.
3. Depending on the number of oocytes used in the ICSI procedure, pipette a corresponding number of 5-10 µL droplets of holding medium.
4. Pipette 2 x 10 µL of SpermSlow™: a primary drop should be close to one end of the elongated bridging drop. A secondary drop can be placed where convenient (for use as a handling drop).
5. Use the pipette tip to create a junction between the primary SpermSlow™ drop and the bridging drop.
6. Introduce a small amount (1-5 µL) of prepared and washed sperm suspension close to the opposite end of the bridging drop (*for low quality sperm samples, using a bridging drop can be omitted, and contact can be created directly between the drop of SpermSlow™ and the Sperm suspension drop*). Use the pipette tip to create a junction between the sperm droplet and the bridging drop.
7. Cover the ICSI dish immediately with pre-equilibrated Liquid Paraffin and either use

immediately or incubate at 37°C for 15 minutes prior to use.

8. Place an oocyte in each droplet of the preferred holding medium.
9. Pre-load the injection pipette with SpermSlow™ from the handling drop.
10. Locate the primary SpermSlow™ drop and work along the edge until the junction zone between the bridging drop and SpermSlow™ drop is reached. This should be evident from the numbers of sperm becoming trapped in the three-dimensional net of hyaluronate.
11. Carefully select a mature spermatozoon. Mature spermatozoa expressing HA receptors will be bound to the hyaluronate in SpermSlow™ and are easily identifiable by their beating tail but limited forward motion. *Spermatozoa moving freely in the SpermSlow™ drop are immature spermatozoa and should not be selected.*
12. Sperm MUST also be selected on the basis of their morphology, as for standard ICSI. It may be easier to select sperm and then re-assess morphology in the secondary SpermSlow™ handling drop before injection.

NOTE: It is suggested that the ICSI injection pipette is washed/rinsed with clean holding medium by aspirating medium into the first 10-20 mm of the pipette in a clean drop. After 1 minute the medium can be expelled and then replaced by aspirating SpermSlow™. This avoids sperm and SpermSlow™ adhering to the inside of the injection pipette.