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English

PICS' Sperm Selection Device

Instructions for Use

Manufacturer: Biocoat, Inc., 211 Witmer Rd., Horsham, PA 19044USA

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Intended Use: To the treatment of infertile couples by Intracytoplasmic Sperm Injection (ICSI), the PICS' Sperm Selection Device is indicated for the selection of mature sperm for injection.

Principle of the Device: Hyaluronan is a main component of the cumulus oophorus matrix that surrounds the oocyte. The head of a mature sperm carries a hyaluronan-specific receptor that enables mature sperm to bind to hyaluronan (1). In contrast, immature sperm **do not bind.** Mature sperm exhibit a high DNA chain integrity (2), a normal frequency of chromosomal aneuploidies and provide a potential contribution to the fetal genome comparable to that of sperm selected by the zona pellucida during natural fertilization (3).

In the usual practice of ICSI, sperm are visually selected for injection on the basis of their morphology and motility. However, this selection does not reflect the genomic integrity of the sperm and its ability to provide the best paternal contribution to the zygote. The PICS' Sperm Selection Device provides a means to select mature sperm based on their ability to bind hyaluronan. Research has PICS' Sperm Selection Device mimics the natural binding of mature sperm to the cumulus oophorus, an important selective step in natural fertilization.

Description: The PICS' Sperm Selection Device is a polystyrene culture dish with three microdots of hyaluronan attached to the interior bottom. Three locating lines embossed on the bottom exterior of the dish facilitate the location of the microdots. The microdot is found in an area approximately 2 mm wide and 3 mm long projecting from the end of the locating line. The device is sterile. Sterility Assurance Level 10⁻⁶, essentially free of endotoxin and non-toxic to mouse embryos.

Preparation for use: Hydrate the hyaluronan microdots by placing single 10-µL droplets of Human Tubal Fluid (HTF) containing at least 5 mg/ml. serum protein or other suitable sperm diluent at the end of each locating line, opposite the area where the microdot is situated (Figure 1). Alternatively, the sperm suspension can be added directly to the microdot. Drops of Phosphate Buffered Saline (PBS) or other fluids useful for manipulating sperm may also be placed elsewhere on the dish at this time. Carefully flood the dish with tissue culture oil to prepare it for use. Hydrating the microdots before applying the sperm suspension ensures that sperm will bind to them. However, sperm suspensions with high protein content may cause the hyaluronan microdots to become sticky. Sperm suspensions with low protein content will not cause the hyaluronan microdots to become sticky. Hydrated hyaluronan microdots remain sticky for approximately 30 minutes after the addition of the sperm suspension. Hydrated hyaluronan microdots are not affected by the addition of culture media, sperm washing solutions, or sperm preparations containing human serum albumin. Hydrated hyaluronan microdots are not affected by sperm preparations containing human serum albumin.

Using the PICS' Sperm Selection Device: Add the sperm to the prepared hydrated microdot in a volume equal to or greater than that used to pre-hydrate the dot (approximately 10 µL). Place the sperm suspension directly over the sperm to the edge of the hydrating drop at the bottom of the dish under the oil and spread the sperm. Place the sperm in a volume equal to the hydrating droplet immediate mixing and delivery of sperm to the vicinity of the microdot is assured. If the sperm are delivered in a smaller volume at the edge of the drop, greater than 30 minutes may be required for the sperm to swim through the droplet to the microdot. Once bound, hyaluronan-bound sperm are easily identified: they exhibit no progressive motion (progressive motion is lost upon binding).

Factors governing sperm binding: To rapidly populate the microdot with bound sperm, place approximately 100,000 hyaluronan-binding sperm per mL (approximately 1,000-2,000 sperm in 10-20 µL volume) in the sperm suspension. See Figure 2. As time passes, the number of bound sperm will increase as more swimming sperm make contact with the hyaluronan microdot.

Sperm Location: Sperm bound to the hyaluronan microdot is a physical barrier to which many sperm will bind since this is usually the first point of contact. It is sometimes difficult to distinguish whether the sperm are bound to the surface or swimming against the edge of the microdot. You may be sure of selecting bound sperm by selecting them from the **interior** of the microdot.

Obtaining a good yield of bound sperm: The ability of bound sperm is too high or too low for good sperm selection, dilute or concentrate the prepared sperm sample and use the adjusted sperm sample to seed the next microdot. Three microdots are provided on each PICS' Sperm Selection Device to give a sufficient quantity of bound sperm.

Hyaluronan on PICS' Sperm Selection Device and its relevance to sperm selection: Hyaluronan is a component of the cumulus oophorus matrix. Hyaluronan is chemically identical to the hyaluronan found in other tissues. Hyaluronan is a non-immunogenic, non-toxic, non-sulfated glycosaminoglycan composed of alternating units of D-glucuronic acid and D-N-acetylglucosamine. Hyaluronan is the only glycosaminoglycan not covalently bound to a protein

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