

Nidacon News

The news letter from your ART supplier • No 1 • 2024

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How safe is a PureSperm gradient?

PureSperm contains colloidal silinized silica. That is, nano particles of amorphous silica with silane modified surfaces that stay in the dispersion. Silane is used since it can form very strong bonds with the silica surfaces.

Silane-coated silica particles are commonly used in many different applications. Some of the more common being:

1. Cosmetics and Personal Care Products
2. Pharmaceuticals
3. Coatings and Adhesives
4. Rubber and Tire Industry
5. Food and Beverage Industry
6. Catalysis in chemical processes
7. Environmental Remediation

Silica is the most common nano material used and is produced in millions of tons each year; this includes the silane coated silica. Since this material is so common its safety is very important and has also been widely studied.

– One study in which the researchers used human monocytes to explore the effect of silica nanoparticles, it was found that silica particles can trigger inflammation. However, these toxic effects were mitigated by silane modification of the particles. (Gupta et al., 2023) In addition, silane by itself can be toxic however, once properly coated onto the silica particles the toxic effects are minimized.

– Another study looking at seven different types of commercial colloidal silica products, with different surface chemistries and particle sizes and found that they do not exhibit toxicity to various organisms within a certain concentration range.

The main finding was that Silane-modified particles showed no cytotoxicity. This lack of toxicity might be due to reduced free silanol groups on the particle surface and increased steric hindrance, preventing contact with cells. This observation aligns with previous studies on silica nanoparticles in human toxicology.

These findings suggest that silica nanoparticles generally have low ecotoxicity. (Book et al., 2019)

Statement by one of the manufacturers of silica. In toxicological tests performed by the manufacturer of silica it has been shown that:

1. **Skin exposure:** An in vitro study performed on four different types of colloidal silica (including unmodified and modified silica) showed that the dermal absorption of silica from any of these formulations was negligible.
2. **Sensitization:** When performing a Local Lymph Node Assay on a silane surface modified silica it was shown not to be a skin sensitizer.
3. **Genotoxicity:** The same silane modified silica was used in three in vitro genotoxicity studies resulting in no genotoxic potential.
4. **Environmental toxicity:** The environmental acute aquatic toxicity has been shown to be low. Colloidal silica can be considered environmentally safe.

When adding all this data to the toxicological tests that Nidacon has performed on PureSperm it can be concluded that silinized silica is a safe material to use for separation of spermatozoa by density gradient centrifugation.

Future Directions:

– Ongoing research focuses on further optimizing density gradient centrifugation protocols, improving sperm selection methods, and exploring its application in emerging ART procedures.

Density gradient centrifugation for sperm separation has revolutionized fertility treatments, offering a safe, effective, and standardized approach to sperm preparation for ART procedures. Its continued refinement and adoption contribute to improving outcomes for couples seeking fertility assistance.

References

1. Gupta, G et al, Exploiting Mass Spectrometry to Unlock the Mechanism of Nanoparticle-Induced Inflammation Activation. ACS Nano, 17(17), 17451–17467.
2. Book, F. et al. (2019). Ecotoxicity screening of seven different types of commercial silica nanoparticles using cellular and organismic assays: Importance of surface and size. NanolImpact, 13, 100–111.



Microbiome testing – any role in IVF?

Several publications have shown that testing of the endometrial microbiome can be a valuable tool for increasing implantation.

Bacterial cells in the human body account for 1-3% of total body weight and are at least equal in number to human cells. Recent research has focused on understanding how the different bacterial communities in the body (e.g., gut, respiratory, skin, and vaginal microbiomes) predispose to health and disease. The microbiota of the reproductive tract has been inferred from the vaginal bacterial communities,

and the uterus has been classically considered a sterile cavity. However, while the vaginal microbiota has been investigated in depth, there is a paucity of consistent data regarding the existence of an endometrial microbiota and its possible impact in reproductive function.

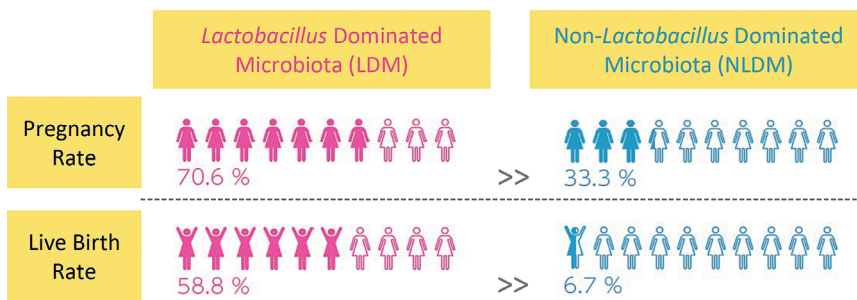
The vaginal microbiota was first identified in 2002 by molecular methods used to detect

nonculturable bacteria. A normal vaginal microbiota is defined by the presence of bacterial species of the *Lactobacillus* genus that are commonly associated with a healthy genitourinary status. The vaginal microbiota typically changes throughout the menstrual cycle, depending on factors such as vaginal hygiene, sexual activity, use of intimate products, and underwear composition; greater microbiota stability is associated with the estradiol peak at ovulation and progesterone rise in the midluteal phase.

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Lactobacillus and Reproductive Outcomes

The study provides strong evidence for the vital role that *Lactobacillus* plays in determining pregnancy outcomes.



• 35 infertility patients undergoing IVF at IVI Valencia clinic in Spain.

However, alterations in the vaginal microbiota can lead to several pathologies. For example, bacterial vaginosis (BV) is a vaginal syndrome produced by the overgrowth of anaerobic bacteria.

Recent studies have shown interest in the presence of microorganisms within the endometrial cavity, an anatomical niche where low-biomass microorganisms could modulate the local immune environment of the uterus. This may influence the implantation of the embryo and the initial formation of the placenta, potentially affecting fertility and the development of obstetric complications in later phases of gestation.

Study from Moreno et al showed a link between the endometrial microbiome and pregnancy outcomes. The existence of non-Lactobacillus bacteria in the endometrium was correlated with negative impacts in reproductive function.

To our knowledge, this work is the first comparative study using next-generation sequencing. The results show evidence that NLD endometrial microbiota is associated to negative reproductive outcomes in IVF patients when compared to those with LD endometrial microbiota.

If you want to know more, visit Nidacon at ESHRE, 7th-19th of July, 2024, Amsterdam, Netherlands, booth no 12076.

Reference
Evidence that the endometrial microbiota has an effect on implantation success or failure. Moreno et al American Journal of obstetrics & Gynecology 2016.

Descriptive characteristics of subjects, cycles, transfers, and outcome results

Characteristics	LDM n=17	NLDM n=15
Age	40.06 ± 3.47	39.00 ± 5.09
Previous pregnancy	1.71 ± 2.44	1.53 ± 2.32
Previous miscarriages	1.53 ± 2.21	1.14 ± 1.56
Mature oocytes/cycle	11.94 ± 4.27	10.20 ± 4.81
Fertilisation rate	77.34 %	77.12 %
No of embryos for transfer	1.65 ± 0.49	1.73 ± 0.59
Pregnancy rate/transfer	70.6%	33.3 %
Implantation rate /transfer	60.7 %	23.1 %
Miscarriage rate	16.7 %	60 %
Live birth rate/transfer	58.8 %	6.7 %

Values are mean ± SD unless otherwise noted. LDM - Lactobacillus Dominated Microbiota, NLDM – Non Lactobacillus Dominated Microbiota.

Saving the Wood Bison with PureSperm

Historically, wood bison were found across the boreal forests of northwestern Canada and Alaska. Due to changes in habitat, herds are now small and disconnected and remain only in northern British Columbia and Alberta as well as southern Northwest Territories and Yukon.

The bison population, whose numbers may have reached upwards of 40 million, is reduced to 300 animals in the early 20th century. Over the past 100 years, conservation efforts have been performed to restore the wild bison in North America, but infectious diseases such as brucellosis that are widespread in many herds present a problem for researchers who are working to save the bison.

Livestock and Forage Centre of excellence's Native Hoofstock Unit use the PureSperm product for bovine called BoviPure to clean the samples from viruses and bacteria.

BoviPure, a density gradient medium based on the same silane coated silica medium that is used for PureSperm but using a method optimized for the bovine spermatozoa.

BoviPure is quite common in the cattle industry to separate motile, viable sperm, as well as other harmful content. Same way that it is used for human sperm separation.



Rhinoceros Sperm Cryopreservation



Nidacon is enthusiastic about contributing to rhinoceros preservation efforts at a time when extinction looms for several rhinoceros' species.

Researchers at the Leibniz Institute for Zoo and Wildlife Research, Berlin, Germany have made significant strides in improving cryopreservation techniques for rhinoceros' sperm, which play a pivotal role in safeguarding species facing threats of extinction and poaching.

In a comprehensive study, three freezing extenders were tested on sperm obtained from 14 bulls. Among these, BotuCrio, containing glycerol and methyl formamide, emerged as the most effective, yielding post-thaw total and progressive motility rates of 75.3% and 68.5%, respectively.

BotuCrio is a Nidacon cryoprotectant medium for equine sperm, based on a novel and innovative formulation which was developed over many years of research and fertility trials at the State University of São Paulo, Brazil.

ProInsert

ProInsert facilitates density gradient preparation and pellet retrieval, reduces the risk of recontamination during retrieval of sperm pellet, and reduces the time for completing a density gradient preparation of a semen sample, including sperm retrieval, by almost half.

It is a unique product but unfortunately due to changes of the outer tube by our supplier, it cannot be used together with the insert. We are working hard on finding a replacement, but it will probably take some time.

Therefore, it will not be possible to order Proinsert until later this year. We'll keep you informed and hope for a quick solution.



New members of the Nidacon team

Madeleine Holmberg and Sofia Liman both with a lot of experience from pharmacy has recently joined us at Nidacon. They will ensure that our production is up to date and that all our products maintain the high quality that you are used to.



Madeleine Holmberg



Sofia Liman

Nidacon will be closed 8-10th of May due to national holiday.



Coming up

■ Nordic IVF Laboratory Society

3rd-4th of May, 2024, Copenhagen, Denmark



Nordic IVF Laboratory Society

■ 14th biennial ALPHA conference

30th May- 2nd of June, 2024, Lisbon, Portugal



■ ESHRE 40th annual meeting

7th-19th of July, 2024,
Amsterdam, Netherlands



Science Moving
People
Moving Science

■ XXVII Nordic Fertility Society Meeting

15th-17th of
August, 2024,
Oslo, Norway



► Who to contact



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