

Nidacon News

The news letter from your ART supplier • No 2 • 2015

► Storage and shelf-life of Nidacon products

We receive many questions regarding storage and shelf-life for all our products. Nidacon has always tried to provide products which are convenient for our customers, products that are easy to transport, store and have a long shelf life. Therefore, most of the products have a shelf-life of one to two years at room temperature and can be stored and transported at room temperature.

All ingredients are chosen for their temperature tolerance and their stability in aqueous solution. None of the ingredients react chemically with each other to form less stable molecules. None of the ingredients are less stable in ionic form, i.e., when dissolved in an aqueous solution.

Rigorous shelf-life testing has been carried out in Nidacon's lab to ensure that the theoretical stability of the salt formulation is matched by their actual stability when combined in the product.

To store the unopened bottles at refrigeration temperature (2-8°C) would do absolutely no harm to the contents. On the contrary, refrigeration of the unopened vial would only prolong the shelf-life, although this is not necessary for the shelf-life recommended on the label.

How do we establish shelf-life?

The shelf-life of our products is determined using many samples from the same batch of the product and these samples are tested directly after production, after storage at room (ambient) temperature and at several time intervals thereafter. At every stage the product needs to pass the tests, having the same requirements as for the new batch. A two-year-old PureSperm® is just as good as a one-week-old PureSperm®.

We have, through extensive testing, assured the quality even after transports at extreme temperatures.

Our shelf-life test consists of;

- pH measurements
- Osmolarity
- Human Sperm Survival tests/Blastocyst tests
- Sterility
- Endotoxins
- Visual inspection (colour, precipitation etc.)

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Transportation

For the transportation we have carried out tests where all products have been stored either frozen or at 50°C for 5 days. After 5 days the frozen products were thawed and all tested in our lab using the protocol for biological batch analyses, the same as used for the release of all products and for shelf-life testing. After performing the tests, we were assured that all products can be transported at room temperature, even at more extreme weather conditions.

But what to do after the product is opened?

After opening the bottle in a sterile environment (aseptic techniques, clean room, LAF-bench), the reclosed bottle should be stored at refrigeration temperature as a safety precaution against unintentional contamination. If an opened and reclosed bottle has not been contaminated during removal of some of the content, and if the bottle is sealed and stored thereafter at refrigeration temperature, then the expiry date provided on the bottle should remain applicable to the remaining content.

Are we really sure that this is correct, most companies recommend only seven days use after opening?

We are sure, again a lot of studies have been done where we have opened, pipetted and closed the product several times during the shelf life of each product. Quite time consuming tests but well worth the effort. No products were affected in any way.



Product Specialist
Ms. Ann-Sofie Forsberg
Direct +46 31 703 06 42
ann-sofie@nidacon.com

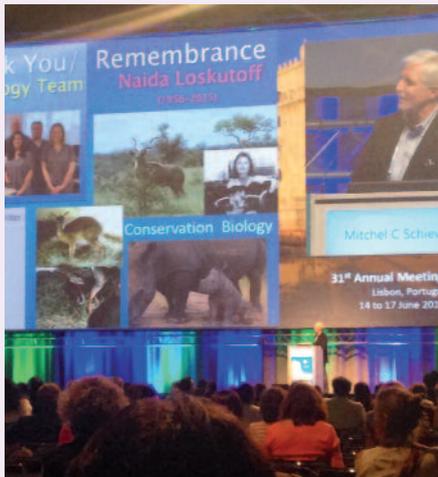


Dr. Naida Loskutoff

The inventor of the Nidacon ProInsert was Dr. Naida Loskutoff, research manager at the Henry Doorly Zoological Park in Omaha, Nebraska. Most unfortunately, she is no longer with us.

During the ESHRE meeting in Lisbon, Dr Mitchel C. Schiewe, the Scientific Laboratory Director at Santa Monica Fertility gave a short presentation summing up her research activities, including her life-long work in the field of reproduction and conservation biology.

Naida Loskutoff was a very special, open-minded person, who dedicated her life to species conservation research both in North-America and South Africa. It was this endeavour that resulted in her invention.



We at Nidacon have been very privileged to collaborate with her over a number of years, being involved in the final design and production of the product called ProInsert™. We convey our condolences to all of her relatives, research colleagues and close friends.



Chief Executive Officer
Dr. Paul V. Holmes
Direct +46 31 703 06 31
paul@nidacon.com

Northern Colorado bison project uses high tech breeding to halt disease and conserve an icon

A small herd of purebred American bison will be reintroduced into the Soapstone Prairie Natural Area in the Laramie Foot-hills this fall.



The herd is part of a project with the aim to reestablish a healthy herd into what used to be its natural habitat.

The breeding has been done by In Vitro Fertilisation and embryo transfer and the sperm are cleaned with BoviPure and Pro-Insert™.

The method for removing pathogens in semen was first developed by Dr. Naida Loskutoff at the Henry Doorly zoo.

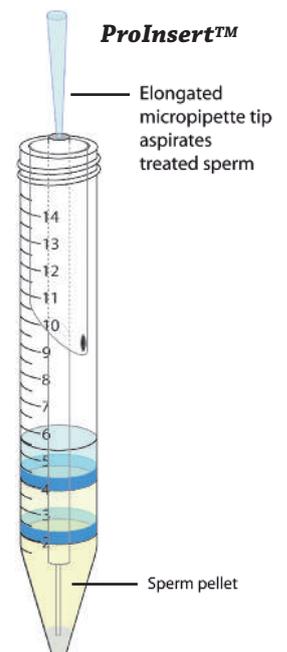
The method for removing pathogens in semen was first developed by Dr. Naida Loskutoff at the Henry Doorly zoo. Further development of the method for bison and in this case the Brucella (*Brucella abortus*) bacteria, which pose a threat to bison herds, was done by Jennifer

Barfield at the Department of Biomedical Sciences at the Colorado State University with the help of us at Nidacon.

There is a similar project ongoing at the University of Saskatchewan, Canada, led by Dr Greg Adams.

Both projects are being supported by different government agencies in the respective countries.

Nidacon is very proud to be a part of the restoration of such a North American icon.



► The "Battle Bag"

Do you have a plan when crisis strikes at your workplace?

In the IVF industry it seems even more relevant that one should, in light of what clinics and patients have riding on these treatments.

Last week in Windsor, UK, I attended the first meeting on Management Tools for Large and Expanding Art Clinics.

More than 60 IVF centres from the UK and Europe were present and together a variety of interesting topics regarding management quality, risk management, and regulation of lab design were discussed. These

are all very important topics to consider in our daily work in order to offer good quality and reliable service to our patients.

While at the same time helping to mitigate the risks associated with the type of technology we work with.

I want to highlight here the great idea implemented by Jessop Fertility, Sheffield, UK. The idea is based on the concept of "Battle Bag". The "Battle Bag" is defined as a lightweight load carrying system designed for infantrymen to carry enough ammunition and ancillaries: such as medical supplies and spare batteries.

This idea is relevant for IVF clinics in order to continue "business as usual" when a potential crisis strikes; while at the same time maintaining the standards which meet your quality management system.

The first step is to define all the potential risks within your IVF center in all the different areas of operation and implement a plan of action to mitigate those risks. Secondly, implement periodical risk meetings. During the meetings have a bag with all of the

potential risks written down and pull out some of the risks in a lottery style. When the risks are revealed it now becomes time to work together in order to solve the potential crisis. This will help identify everyone's responsibilities in each process and highlight what each should do when a crisis arises. A few examples could be what to do if there is an electric power failure or what to do in the lab when one of the alarms goes off.

This concept is very pedagogical and can allow us to always be ready to face a crisis and solve it in the most effective way possible.

This will help identify everyone's responsibilities in each process and highlight what each should do when a crisis arises.

Our daily work involves patients who have their hopes and dreams riding on the outcomes of their treatments. We must provide adequate conditions so they can feel comfortable and secure during every step of their treatment. Adopting such measures which address crisis planning and the mitigation of risks takes a very important step in the enhancement of the quality of service we can provide.

It is very important to remember that no matter what quality management system you use or what kind of certification you have the important issue is to be prepared to react to any situation.



KAM, Latin America
Mr. Mauricio Lucena
Direct +46 31 703 06 39
mauricio@nidacon.com

► You're Kidding!

Medical Clown Increases Pregnancy Rates with IVF

A study of 229 Israeli women undergoing in-vitro fertilization (IVF) found that a 15-minute visit from a trained "medical clown" immediately after embryo transfer increased the chance of pregnancy to 36%, compared with 20% for women whose embryo transfer was comedyfree.

After controlling for factors such as the women's age, the nature and duration of their infertility, the number of embryos used and the day of transfer, researchers found an even greater effect of therapeutic laughter: the women who were entertained by a clown were 2.67 times more likely to get pregnant than those in the control group.

The quasi-randomized controlled study was published in Fertility and Sterility and led by Israeli researcher Shevach Friedler. It is considered only quasi-randomized because the timing of the recruitment of the control group was slightly different from that of the clown group.

In the trial, the professional medical clown – who was dressed as a chef and performed the same light routine each time – visited patients during the half-hour after embryo transfer, when women typically stay lying down. The idea was to help reduce women's stress, which laughter has been shown to do, and, hopefully, reap the physiological benefits.

Researchers have long known that stress can sometimes play a role in infertility. The condition not only creates stress by itself, but treatments for it can often add to the burden.

It's possible that the more relaxed a woman is after the transfer, the more likely the embryos will implant. In previous research, a Cochrane review of studies found, potentially stress-relieving acupuncture treatments done at the time of embryo transfer have nearly doubled pregnancy rates.

It would be fun if it worked, we could all need a clown now and then. Either way, though, as far as treatments go, at least a clown is non-invasive, cheap and unlikely to do harm. And if it works, a lot more people struggling with infertility will have something to smile about.



The women who were entertained by a clown were 2.67 times more likely to get pregnant than those in the control group.

Fun facts about Nidacon:



Nidacon has only one office and it is located on the west coast of Sweden in a city called Mölndal, close to Gothenburg. In contrast to the company's location, only one fifth of Nidacon's employees have been born and raised in Sweden.

Our CEO, Paul Holmes was born in Britain, raised in Canada, and since early adulthood has lived in Sweden.

This international influence has laid ground for the global diversity we see with our employees here at Nidacon.

The rest of Nidacon's workforce is represented by the following nations: Argentina, Britain, Canada, Colombia, Finland, India, Japan, Poland and Russia. Quite the cultural mosaic.

With this cultural diversity it is no surprise as to why we have had great success cooperating with researchers and clinicians all over the world. Not to mention our ability to understand the market from a global perspective.

Web News

Important announcements, recent changes and relevant news can sometimes get lost in the general flow of information.



So far, we have not had a dedicated section on our website to address this kind of information. In light of this, we have decided to create a simple platform to ensure this type of information is easily accessible for you.

From now on you will be able to see these important updates on the homepage of the Nidacon website and a link which will lead to the full text.



Marketing Manager
Mr. Oscar Rymo
Direct +46 31 703 06 33
oscar@nidacon.com

Who to contact



Product Specialist
Ms. Ann-Sofie Forsberg
ann-sofie@nidacon.com
Tel: +46-31-703 06 42



Logistics
Mr. Dennis Johansson
dennis@nidacon.com
Tel: +46-31-703 06 37



Upcoming events



- ASRM 2015, October 17 to 21, 2015, Baltimore, Maryland.



- SASREG -National Congress, October 30-1 November, 2015, Johannesburg, South Africa.



- ALPHA- the 11th Alpha Biennial Congress, May 5-8, 2016, Copenhagen-Denmark.

