

Nidacon News

The news letter from your ART supplier • No 1 • 2021

Contents

The dawn of a new era _____	1
Optimization of your IUI results _____	2
New addition to Nidacon's Equine product line _____	2
Focusing on the health and well-being of men _____	3
Shortage of ProInsert _____	4
Coming up _____	4
Who to contact _____	4

The dawn of a new era

Medical Device Regulation and its possibilities in the IVF-field



The Medical Device Regulation (MDR) is on the way to be implemented in Europe and we have since a couple of years back worked towards this.

The implementation date is now May 26th, 2021. We believe this implementation will be a joint effort for everyone working in the Medical Device field and in our case the IVF-field in Europe. We will all play a role.

As part of this implementation, they have developed EUDAMED (<https://ec.europa.eu/tools/eudamed/#/screen/home>) which is an online platform we will all access. We have registered and have received what is referred to as the SRN No. This number refers to us as an economic actor in the European market for medical devices. The EUDAMED is available but only one module so far.

The EUDAMED is one of the key components of fulfilling the MDR. The EUDAMED is a web-based platform that will be composed of six modules related to: actor registration, unique device identi-

fication (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance and market surveillance. To this date only the section relating to Actor Registration has been made available. The following estimated timeline applies for the time being:

Module	Release
Actors	Q1 2021
UDI Devices	Q2 2021
Certificates	Q2 2021
Vigilance	Q3 2021
Clinical Investigations	2022
Post Market Surveillance	2022

We have now registered as an Economic Operator on the EUDAMED website and are now searchable on the following link: <https://ec.europa.eu/tools/eudamed/#/screen/search-eo>

The information included in the EUDAMED Economic Operator registration is very basic but as soon as you have registered you receive a Single Registration Number (SRN No) which will be very important from when the MDR is in place. Nidacon from now on has the SRN No: SE-MF-000001933. This will

be a very important number for all active medical device companies in the European Union.

Everyone will be able to access the information in the EUDAMED. All IVF clinics will for instance be able to see the Post market surveillance and the vigilance data for every product and company registered. This will lead to an increased transparency throughout the European Union, and we believe, if they get it rolling properly, it will be of great benefit

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for all of us. It has similarities to the system in the USA made available from the FDA.

The full MDR is available on the EU commission website (<https://ec.europa.eu/>) but we have also found very handy versions that you can buy from the Qserve Group on the following link (<https://www.qservegroup.com/eu/en/knowledge-center/eu-mdr-booklets>). The MDR will be supported by further guidelines which are published as MDCC:s on the commissions website https://ec.europa.eu/health/md_sector/new_regulations/guidance_en.



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Optimization of your IUI results

Intra uterine insemination (IUI) is performed all over the world as a first choice of therapy for infertile couples.

But success rate is quite low compared to IVF/ICSI, generally 10-20% clinical pregnancy rate /cycle.

Recently, two papers were published regarding optimization of performing IUI. The first is a large study, based on data from 37 553 patients having 92 471 insemination cycles with fresh or frozen sperm between 2002 and 2018. The goal was to find the optimal threshold for the number of post-wash motile sperm that gives the best chance of success.

In the first article, the results, adjusted for age, BMI and stimulation protocol, showed that a total motile count of $\geq 9 \times 10^6$ after preparation was a useful threshold. It was not significantly associated with pregnancy but highly predictive. The authors do however state that it is still impossible to draw definitive conclusions regarding the optimal concentration of motile sperm, but post-wash count may still have a unique value as a tool for improved results.



The second article also looked at potential improvements in the lab, using IDEF* mapping, an activity model including all parameters of the sample preparation.

- Two time parameters were looked at;
- the time between semen production and start of analysis: A threshold of 21 min was found and for
 - the time between semen production and IUI: A threshold of 107 min. was found.

The two time variables are significantly associated, resulting in a doubling of the odds on the pregnancy outcome for the

21 min or less and 1.6 times the odds for 107 min or less.

The results have been shown before and could be due to the rapid rise in osmolality, could increase sperm DNA fragmentation. Avoiding long time intervals both before and after analysis is recommended.

A very short summary of the two papers, I recommend you take a closer look.

References

Clarifying the relationship between total motile sperm counts and intrauterine insemination pregnancy rates, Akhil Muthigi, M.D et al. Fertility and Sterility® 2021 in press

Time intervals between semen production, initiation of analysis, and IUI significantly influence clinical pregnancies and live births, Punjabi et al Belgium Journal of Assisted Reproduction and Genetics 2020

**Implemented Integration Definition developed by the US Air Force in 1998*



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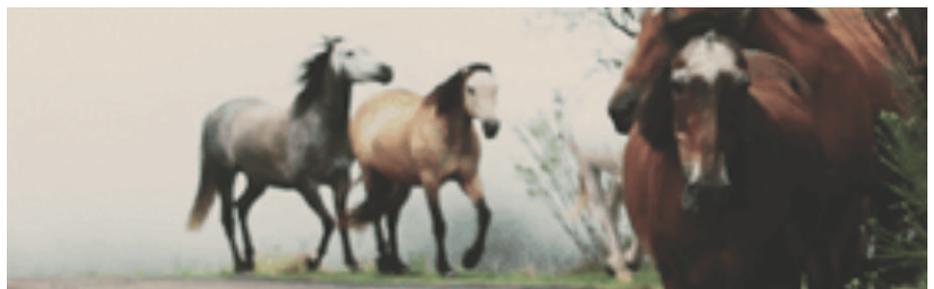
New addition to Nidacon's Equine product line

When processing stallion sperm the ejaculates normally need to be centrifuged in order to concentrate the sperm and to substitute the seminal plasma with an extender.

Some stallions are more sensitive to centrifugation than others, and for this reason, it is common to use a "cushion" to prevent damage to the sperm when pelleting in the bottom of the tube.



The product RedCushion is a fluid of high density. It reduces damage from centrifugation through sperm damping over



the cushion on the bottom of the tube. It produces less compacted sperm pellets with high sperm recovery rate due to the possibility of working with intensity and time of centrifugation above those used in conventional protocols.

It can also be used in the bottom of the tube at density centrifugation with EquiPure™ (the equivalent to PureSperm for horses). Once completed, the supernatant (the plasma/extender portion in the upper section of the tube) can be aspirated, then the cushion (if desired)

removed from underneath the sperm layer. Because it has a reddish coloration, it allows simple visualization of the pellet and its removal.

In collaboration with the Brazilian company BotuPharma, Nidacon has now added Red Cushion to our line of products.



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Focusing on the health and well-being of men

The health and well-being of men is and have been in focus for the last few years.

The United Nations 2030 Agenda for Sustainable Development includes promoting actions that will reduce premature mortality among men as well as improving men's mental health and general well-being. This will help achieve the Sustainable Development Goal (SDG) 3 on good health and well-being, SDG 5 on gender equality, as well as SDG 10 on reduced inequalities.

ESHRE has also started an initiative namely the Male Reproductive Health Initiative (MRHI) which is a global collaboration dedicated to advancing the science and practice of male reproductive medicine. This group consists of very experienced andrologists, and reproductive-medicine scientists and doctors from around the world.



The WHO has put together strategies on the health and well-being of men in the WHO European Region. These strategies include targeting positive engagement of young boys and men with paid or unpaid healthcare, fatherhood, prevention of male-to-male violence and gender-based violence, as well as action concerning sexual and reproductive health.

In all European countries diseases such as cardiovascular disease, cancers and respiratory disease are the leading cause of death and disabilities among men, followed by injuries. Even though premature mortality is declining in the region, a focus in some countries on males aged 30-69 years would help further accelerate progress.

Differences between genders in rates of injury are striking, starting from early childhood, and conti-

nuing throughout the course of life. The rates of injury are also higher in low- and middle-income countries compared to high-income countries, and inequalities related to social class within countries. Seventy per cent of deaths due to injury are in males and, even though male injury mortality rates in middle-income countries are 2.2 per cent higher than in high-income countries, there is no such difference in females. Furthermore, almost seventy-five per cent of all traffic deaths occur among young men under the age of 25 years.

Self-harm and suicide are also significant causes of death and a disease burden among men in the European Region. There is also a substantial variation between and within countries. Suicide is more than three times higher among males than females in all age groups over the age of 15 years. A leading underlying cause is depression.

Ill-health and health inequities among men are strongly influenced by exposure to risk factors such as alcohol consumption, tobacco and other substance use as well as overweight. Gender norms and roles and socioeconomic background, all strongly affect these risk factors.

Most evidence show that men participate less in preventive health services, seek medical help at a later stage than women and receive more informal care. The way

health systems respond to men's health issues is affected by the design of health services and the setting, as well as the understanding of norms around masculinity and behaviour among health professionals.

There is a general understanding that men's reproductive health needs are not being met.

There is a general understanding that men's reproductive health needs are not being met. This includes relation to family planning, prevention and treatment of sexually transmitted infections, as well as maintaining healthy sexuality and fertility. A lack of knowledge prevents men from contacting the health services with these concerns. Even in places where there are specific sexual and reproductive health services available for young people, most of the clients are young women. Gender stereotypes may prevent young men from accessing these services. Women encounter these health services automatically when regular health checks are performed for birth control prescriptions and during pregnancy and childbirth.

The main goals and objectives of the WHO strategy are as follows:

- reducing premature mortality among men due to diseases, plus both unintentional and intentional injuries
- improving health and well-being among men of all ages, while reducing inequalities between and within countries of the region
- improving gender equality through structures and policies that advance men's engagement in self-care, fatherhood, unpaid care, violence prevention as well as sexual and reproductive health.



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Shortage of ProInsert

Due to popular demand and increasing lead-time for component deliveries (due to the pandemic), we have a shortage of ProInsert.

We are working as best we can to fill up the ProInsert storage as much as possible but, unfortunately, we do not have ProInsert in stock at the moment. We will release a new batch of ProInsert™ during the second week of June.

The manufacturing units and suppliers are being booked for supplies necessary for the handling of the pandemic.

We hope this does not cause too much inconvenience and you can rest assured that we are doing our very best to amend this situation.

Take Care Nidacon Team



Coming up

- ALPHA 2021 Biennial conference
16-19th of September Sevilla Spain



- 77th ASRM Scientific Congress & Expo
16-20th of October, 2021
Baltimore, MD, USA



Change of Business Administration System

In May, a new system will be launched at Nidacon.

This means that documents like order confirmation, invoice etc. will be slightly different. Let us know if there is any information that is

missing in the new formats. You will also be given new customer numbers in this system, can be found on the first invoice after 3rd of May. We will still have the old ones, no problem if you use them for orders.

ORDER CONFIRMATION						
Date	Order No.	Customer No.	Page 1			
21.04.2021	01010102	1247				
Delivery address: Test Customer test street SE Sverige			Customer: Test Customer test street SE-10000 stock Sverige			
Your ref: Test Customer	Your Order No.: 55555	Delivery date: 23.04.2021				
Order:	Terms of delivery: Frist omkosta, punkt till för.	Mode of transportation: UPS Server	Terms of payment: 30 dagar netto			
Item No.	Description	Qty.	Unit	Price/unit	Amount	
P5100-100	PureSperm 100, 1 x 100 µL batch: 095290 Exp.date: 211217	10	SE	162.00	1 620.00	
Freight Cost				Order Value	1 620.00	
Tel: +46-31-703 06 30		VAT No.: SE55649322901		Bank: Handelsbanken		SWIFT: HSBSE33
431 37 Mölndal		E-mail: contact@nidacon.com		RUC No. Change: 4 number		BIC: HANS233
Sweden		Telefax: +46(0)31-703 06 30		IBAN: 5248 4000 00		IBAN: 5248 4000 0000 5322 5799

INVOICE						
Date	Order No.	Invoice No.	Customer No.	Page 1		
21.04.2021	01010102	F1610001	1247			
Delivery address: Test Customer test street			Customer: Test Customer test street SE-10000 stock Sverige			
Your references: Your order No.: 55555 Your ref.: Test Customer Mail: Your VAT No.: 89591989 Inv. del. date: 21.04.2021			Our references: Our order No.: 01010102 Our ref.: Order date: 21.04.2021 Del. date: 21.04.2021 Terms of payment: 30 dagar netto By air: Express Terms of sale: CIP - Frist omkosta, punkt till för.			
Item No.	Description	Qty.	Unit	Price/unit	Amount EUR	
P5100-100	PureSperm 100, 1 x 100 µL batch: 095290 Exp. date: 211217	10	SE	162.00	1 620.00	
After double interest rate will be charged with: 0,00 %				Invoice rate: 8.979	VAT in SEK:	0,00
Net amount				1 620,00	Freight	0,00
Rounding				0,00	AMOUNT EUR	
Total: +46-31-703 06 30				VAT No.: SE55649322901		Bank: Handelsbanken
431 37 Mölndal				E-mail: contact@nidacon.com		RUC No. Change: 4 number
Sweden				Telefax: +46(0)31-703 06 30		BIC: HANS233
				IBAN: 5248 4000 0000 5322 5799		IBAN: 5248 4000 0000 5322 5799

Who to contact



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