

PREFACE

Dear Friends,

In this July edition, we have good news and kind of expected update.

Some of our Gynemed products are improving with new features, however one of our products will leave the Gynemed family.

Furthermore, we wanted to show you how important a warning system for Cyrotanks is. In the year 2018 something very terrible happened in the USA, as you can read from the article of the Washington Post.

Due to COVID 19 we did a second year with an online ESHRE congress. Gynemed was participating with a virtual booth, which you can still visit. Hopefully we can all meet next year in person as usual.

Gynemed will be attending the ALPHA meeting, our first international face-to-face congress since the beginning of the pandemic.

Stay safe, enjoying your summer!

TrakJector 2021

Micromanipulator from Gynemed/Hamilton Thorne



After constant development, we can now present to you the latest version of our micromanipulator, the 'TrakJector'.

Ratingen-based Luigs & Neumann (L & N) has been known in the life sciences (LS) sector for its innovative micromanipulators for decades. With helpful feedback from our global IVF clients and together with L & N, we have been able to equip the Trakjector 2021 with the following features:

- New angling from 0° to 50° that can be simply adjusted using a knurled screw, while pipette tip focus is hardly impacted at all
- Revised double screwed spindle motors for even more stability without impacting precision
- Pipette holder can be quickly inserted and removed thanks to a simple click system and spring holder
- Convenient exchanging of clamped glass pipettes also possible via 'swing out' mechanism on pipette holder
- Exceptional precision with a deviation of $\leq 1 \mu\text{m}$ within 24 hours. (measurement from LS sector patch clamp technique)



Thanks to electronic manipulator control, it's possible to temporarily deactivate the Y axis to ensure absolute parallel movement along the X axis to optimise injection into the egg.

Of course, various speeds can still be set and saved.

Questions about our TrakJector? We'd be happy to hear from you.



Trackballs

15 million dollar damage compensation awarded in cryotank failure case

The safety of cryotanks has frequently been discussed at Gynemedia, and is an ongoing topic for you in clinics; whether that's in relation to inspections, selecting monitoring systems or choosing insurance policies.

In March 2018, a cryotank at the Pacific Fertility Center in San Francisco failed. The oocytes and embryos frozen within it may have thawed. The level of damage was unclear. We now have a ruling for this case.

The Washington Post reported on the 12th of June that a jury in California awarded 5 of the patients a total of 15 million dollars in damage compensation after 4 years of deliberations. This ruling could have far-reaching consequences for the poorly regulated US IVF market. This ruling is the first time that responsibilities have been

clearly outlined in any such storage cases and the loss of embryos and oocytes has resulted in damage compensation. Earlier cases as well as cases of mix-ups have ended up with settlements. The result of these court proceedings could lead to increased focus on the billion-dollar 'reproductive medicine' sector and its control.

As described in the article, there is no regulatory authority in the USA that oversees assisted reproduction. There is just one federal law regulating how achieved pregnancy rates may be advertised. Following the recommendations of the ASRM, for example, is voluntary and there is no power to enforce these.

At state level, the main goal is to regulate research on and using stem cells, whereas reproductive medicine, its processes and practices

are minimally regulated. 'There is no licensure requirement, there's no monitoring regime, no data registry for adverse events like this one,' says Dov Fox, Director of the Center for Health Law Policy & Bioethics at the University of San Diego. 'There's no system of warnings or disclosures or any other measures to track reproductive facilities or hold the specialists accountable.' Political decision makers in the USA are possibly hesitant to begin drafting new regulations after years of a casual approach.

The character of this jury ruling and the benchmark it has set could now lead to a change of attitude.

You can find the whole article by Derek Hawkins here:

<https://www.washingtonpost.com/health/2021/06/11/fertility-clinic-egg-embryo-verdict/>.

New discoveries in sperm diagnostics

We always welcome suggestions for improvements, and always try to integrate these ourselves or in our collaborations with our suppliers.

We have successfully done so again in our work with Antigenes: from the new production of SemenHOS, which will foreseeably be available from late summer, 1

x 20ml pack will now be available for the same price as the old 20 x 0.9ml packs. Furthermore, positive controls for the SemenMar, SemenIgG and SemenIgA antibody tests are also now available. You can either order these separately or in the kit together with the tests. If you're interested in a quote, just let us know!



SemenMar - SemenIgA - SemenIgG

GM501 EmbryoStore ... time to say goodbye!

Slow freezing and, therefore, the GM501 EmbryoStore has been a companion to you and us for many years.

However, the slow freezing method has left the limelight over the last few years due to the development and establishment of vitrification. It has therefore become more and more difficult over recent years to achieve the necessary case numbers for the clinical evaluations required for medical device approval.

The introduction of the new European Medical Device Directive and the related recertification of all medical products has led to our decision to shut down the production and marketing of the GM501 EmbryoStore Freeze and Thaw when its CE certificate runs out on the 1st of October 2023. In order to help you plan as much as possible,



GM501 EmbryoStore

we are informing you now with plenty of notice. The EmbryoStore Freeze will be available until November 2022 (expiry date). The thawing media (EmbryoStore Thaw 1-3) will remain available, with production foreseeably ending in autumn of 2023. The media's ex-

piration date will therefore fall in spring of 2025.

We'd be happy to help if you have any questions. If you are interested, we can also present various options for the vitrification of oocytes and embryos. Get in touch!

ESHRE – ALPHA

If you're holding this Gynemed in your hands, then ESHRE 2021 is already over. However, you can still visit our virtual industry trade fair stand.

After multiple postponements, the ALPHA conference will also take place in person in Seville on the 16th - 19th of September. Laurence Rivain and Dr Julia Heinzmann would love to see as many of you as possible in person in Spain.



LEGAL NOTE

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