

FOREWORD

Dear reader,
in this latest issue, we're especially happy to be able to introduce a new member of the Gynemed team: Mr Simon Gaisbauer, who will be joining our technical service team.

Furthermore, we've compiled a list of interesting publications for you that show Gynemed DENU tips are a very valuable alternative to standard stripper tips.

We are also glad to be able to announce that the previously advertised Kitazato media, with a shelf life of 12 months, are available now.

Also we have some news from our export department. There are some changes in our team and in ordering that will make the process much more efficient. By the way our quality management system according to ISO 13485 was successfully audited once again.

Finally, we will have a booth at ESHRE – virtual congress, where we do have some tickets left.

We hope you enjoy the lecture and look forward to seeing you at the first virtual ESHRE from 5th to 8th July. We await this experiment with anticipation, and are looking forward to seeing you at the upcoming Reprofacts in Mainz.

Your Gynemed

New to the Gynemed team: Mr Simon Gaisbauer

As of 01.04.2020, Simon Gaisbauer has been supporting the Gynemed GmbH & Co KG team in sales as well as technical support and service.

Simon is a fully trained construction mechanic specialising in construction technology, and was employed at Automotive Zettl in the quality and follow-up departments. Here, he was tasked with various projects in the BMW Dingolfing facility, such as follow-up work on chassis components as well as monitoring compliance with quality standards.

In August of 2017, Simon moved to Vitrolife GmbH in Bruckberg. Vitrolife GmbH is a certified company specialising in the production, sales and installation of lab equipment and consumables for reproductive medicine.

Simon was employed within technical service. His tasks included the technical support of domestic and international clients as well as installing and commissioning lab equipment and software on site alongside servicing and repairing lab equipment operated by Vitrolife GmbH.

The specialist skills he gained in the fields of microscopy, lab equipment and human reproduction as well as a fundamental interest in the latest technical approaches for optimising clinical monitoring and laser systems



Mr Simon Gaisbauer

laid the foundations for a collaboration with the Gynemed GmbH & Co KG team.

In April 2020, Simon Gaisbauer moved to technical service with the support of Dr Tiedemann and Dr Hoffmann as well as colleagues Dr Terzenbach and Mr Jacob.

Tasks included sales and advice consultations, on-site installation and maintenance, answering technical questions about the products sold by Gynemed, and implementing/supporting internal tests of operated devices.

Simon is excited to build on his skills, particularly regarding the CASA systems IVOSTM and CEROSTM, and to supporting existing as well as new clients.

Bisphenol A

Within the approval process for Gynemed DENU tips as a medicinal product, we were confronted with an interesting difficulty.

During the development process for medicinal products, the choice of material plays a key role. The usual material for denudation pipettes is polycarbonate. However, polycarbonate always contains Bisphenol A (BPA). This was critically considered in our risk analysis and in the discussion with our notified body, so an alternative material was chosen. Polyamide, the initial material for Gynemed DENU tips, is BPA-free, and the conformity evaluation process along with CE certification were able to be carried out without issue.

At the same time, it's worth taking a look at the literature:

Bisphenol A (BPA), a chemical substance found in plastic bottles, food packaging and medical products, has long been associated with an impact similar to that of oestrogen. For some time now, the impact of this substance on human fertility has been the subject of scientific research.

A work group at the University of San Francisco recently began researching the effect of BPA on the human endometrium. To this end, cultures were taken of en-

dometrial fibroblasts (hESF) from the uteri of hysterectomy patients whose operations were not due to endometriosis or adenomyosis. The cultures were then treated with BPA, with or without oestrogen and cyclical AMP. The team was able to establish that BPA impacts the genetic expression of various genes, not only affecting oestrogen metabolism but also the differentiation of the hESF cells themselves. (Aghajanova and Giudice – Effect of Bisphenol A on Human Endometrial Stroma Fibroblasts in Vitro)

Dr J. Lamb established BPA levels in 41 couples during their first cycle of IVF. 93% of the women studied had a measurable level averaging 4.2ng/ml. The BPA level was able to be measured in 81% of the men's blood. This averaged 2.2ng/ml, considerably lower than in the women. Correlations within the couples could not be established but there was a trend of inverse association regarding increased BPA levels and the absence of pregnancy. (Lamb et al – Serum Bisphenol A (BPA) and Reproductive Outco-



*Gynemed DENU-Tips -
available in sizes
135µm to 300µm*

mes in Couples Undergoing IVF)

While studies on mammals were able to show that environmental BPA exposure correlates with worsening ejaculate parameters, Shelley Ehrlich was not able to confirm this for human medicine. 71 men from the Massachusetts General Fertility Center collective submitted urine samples for comparison with their semen samples. The BPA level values, averaging 2.41mg/l even when embedded in a pronounced variance, did not correlate with the quality of the spermiogram. (Ehrlich et al – Urinary Bisphenol A Concentrations and Human Semen Quality)

**OFFICIAL
EXHIBITOR
ESHRE / 20**

**We're glad
to your visit!
5. - 8. July 2020**

Hello from the Export Team at Gynemed!

We have some news for you !

From now on, you will receive this newly designed newsletter every two months as part of our famous GYNEMEDIA. We will combine the German, French and English version into one, so you will receive all information which may be of interest to you. It could be that some of the articles are not applicable to your area but please always feel free to send us an inquiry so we can find out if this product or the changes are relevant for you.

As you know the Export team at Gynemed is growing constantly. For a few months now we are three employees in the internati-

onal department: Jessica Wittern (9 years at Gynemed), Katharina Fries since (almost one year) and our newest team member , Vivien Mizel (since March). We are very happy about this team and hope we can support you with all inquiries. To make sure that your orders and questions are answered promptly, we have implemented a new e-mail account: export@gynemed.de. Please use this for all inquiries.

From time to time, you asked us to send you the new certificates, photos etc. To make your life easier and help you with keeping your documentation and websites up to date, we have created a marketing

and document folder for you. , You will receive a login code, where you can always download the respective files. We hope with this new solution, you can keep your websites and brochures updated with new photos and information and provide your customers with current information.

We would be also delighted to receive any suggestions you might have for our homepage. In the near future we would like to add the distributor contact details for each country to the website. Your customers will be able to find quickly the correct business partner. If you don't agree, please let us know.

ISO 13485

GYNEMED GmbH & Co. KG has implemented and maintained a quality management system according to EN ISO 13485 for the development, manufacture, final inspection and distribution of products for reproductive medicine. The certificate was issued by the certification and testing company MEDCERT GmbH.

For the product certification our notified bodies are DEKRA and MedCERT, below you will find an overview which products are certified with each notified body:

The following products under certification with MedCert:

- GM501 Gradients
- GM501 Mineral Oil
- GM501 Bromelain
- GM501 Collagenase
- Micropipettes
- Denu-Tips
- Oocyte Aspiration Needles

The following products under certification with DEKRA:

- GM501 Cult with Gentamicin
- GM501 Cult with Phenolred & Gentamicin

- GM501 Vitri Freeze/Thaw Kits- GM501 Embryo Store Freeze/ Thaw Kit
- GM501 GentleVit Freeze/ Thaw Kits
- GM501 Hyaluronidase
- GM501 PVP
- GM501 SpermActive
- GM501 SpermAir
- GM501 Wash
- GM501 Wash with Phenolred & Gentamicin

Despite the pandemic our quality management system was audited by MedCert at the beginning of June. The topics of the audit were the applicable requirements of the standards and directives (EN ISO 13485:2016 and MDD 93/42/EES) to the current versions of Gynemed's quality management and product documentation.

The audit goals have been:

1. The observation of the conformity of the management system with the quality management system standards.
2. The analysis of the management system's to compliance with applicable legal requirements.

3. The observation of the effectiveness of the management system in terms of achieving the specified goals.

The notified body MedCert decided and pronounced the QM system does work according to the requirements and we are all doing a great job.

Well known fact is also, that the new MDR regulation will go into effect in May 2021. The considerable difference to the present MDD is that as a regulation, the MDR has general validity and immediate effectiveness in all EU member states. Thus, the MDR provides an optimized and standardized regulation for the placing on the market of medical devices, with a stronger emphasis on product quality and safety.

In the new regulation the roles of all partners including distributors are more clearly defined. Therefore we will need to update the Distributor Agreements. We will send the contracts to you by email for review and signing in due time.

First time ever! ESHRE - Virtual Congress

Nearly all of you know us in person due to the yearly ESHRE meetings and you all know how much fun it always has been. This year it will be different due to the COVID-19 pandemic.

ESHRE will not take place in the usual nice personal way, not with a great big pink booth and nice talks with our distributors and customers. We feel very sad about this situation, but we can only make the best of it.

To have at least a little feeling of the ESHRE, we will join the virtual congress with our own booth. It would be great if you would visit us and if you have any questions, please feel free to ask and contact



us at any time. You can register for free as a visitor for the exhibition on the ESHRE website, but furthermore we have a few tickets available for the congress main program for you - first come, first serve.

By the way, what are your opinions on the virtual congress? Do you think it will be a success and will it be our future?

Best regards and stay safe
Your Export Team

Available now!

We've already told you about them, but they're now available:

Kitazato media with a shelf life of one year! To make your planning and inventory so much easier! The VT601 and VT602 media also con-

tain gentamicin, as was in the previously available VT801 and VT802 and now back by popular demand.

There have been no changes to the application or logs, so you can carry on as usual.



Important customer information

Due to the COVID-19 outbreak, UPS can no longer guarantee timely Express or Express Saver deliveries for any domestic, cross-border or international deliveries in Europe.

Please take this into account when placing any orders!

LEGAL NOTE

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