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Connect 2 Cleanrooms support Preclinical and Clinical trials for ArterioSorb™

Connect 2 Cleanrooms latest bespoke modular cleanroom installation supports the development of next-generation bioresorbable cardiovascular scaffold (stent), ArterioSorb™.

ArterioSorb™ is an innovative medical implant product currently being developed by UK medical device SME, Arterius Ltd, to assist in the treatment of coronary artery disease which affected 110 million people and resulted in 8.9 million deaths in 2015.

As the first of its kind in the UK, the bioresorbable cardiovascular scaffold is to be implanted within coronary arteries in order to open blocked vessels, bio-degrading within two years when the healing is complete and no longer needed. The ArterioSorb™ development was supported by a consortium of experts comprising a clinical advisory team; computational design group at Southampton University; polymer process engineering at Bradford University and first- class pre-clinical and clinical institutions.

After recently completing their initial pre-clinical trials, Leeds based Arterius Ltd quickly established the need for a cleanroom to facilitate the next stage of their project and start clinical trials by the end of 2018. As a medical industry requirement, Connect 2 Cleanrooms designed, manufactured and installed a Modular Hardwall panel system at their premises to improve the quality, purity and consistency of their end product.

With an overall footprint of 20.72m², the install included a small external change area which allows operators to gown up in a controlled environment. The main cleanroom area is 4m x 4.4m, ISO Class 8 and controlled by the ECO System with a built in alarm function, providing Arterius with a sustainable approach for their cleanroom. The design incorporates a mixture of hinged doors and sliding doors aiding the flow of material and personnel in and out of the cleanroom and the Arterius logos to the outer panels add personalisation to the room.

The flexibility and ease of the quotation process made the decision to go with Connect 2 Cleanrooms an easy one, stated Dr Naveed Ahmed, Development Scientist at Arterius 'Our decision to use Connect 2 Cleanrooms as the supplier of our cleanroom was down to the rapid response to communications and quote requests, as well as the short lead time. They listened to our needs and made recommendations to best match our requirements.'

'The installation of the cleanroom has impacted our business greatly, it's an asset we are proud to have which will rapidly progress the development of our products to the next stage. It will allow us to manufacture medical device products to the necessary standards of quality.' Naveed continued.

Connect 2 Cleanrooms

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Increased production will meet growing demand for sustainable antibiotics

DSM Sinochem Pharmaceuticals to boost manufacturing capacity at Dutch plant

Building on its commitment to producing antibiotics sustainably in the fight against antimicrobial resistance (AMR), DSM Sinochem Pharmaceuticals (DSP) has announced the expansion of its manufacturing facility in Delft, the Netherlands. The company's aim with this investment is to meet the growing demand for sustainably produced 7-ADCA, the key intermediate for cephalosporin active pharmaceutical ingredients. A new fermenter will be added to the DSP site in Delft, the Netherlands, which will make use of leading-edge technology that is energy efficient and environmentally friendly. DSP expects the new extension to the plant to be fully operational in the last quarter of 2017.

The Delft site produces 7-ADCA, the key intermediate for making the company's sustainable cephalosporin APIs including cephalexin, cefadroxil and cefradine. DSP is the only remaining producer of this intermediate in the Western hemisphere. In the early 2000s, the company revolutionized the industry by introducing a new breakthrough process for the sustainable production of high-quality 7-ADCA. So far this process, based on proprietary technology, is the only one of its kind for manufacturing 7-ADCA worldwide.

Irresponsible manufacturing has been recognized as one of the key causes of AMR due to the uncontrolled release of antibiotics into the environment. In particular, waterways downstream of production facilities may contain significant concentrations of antimicrobial activity, and risk becoming breeding grounds for resistance.

As a leader in the sustainable production of ß-lactam antibiotics, DSP has implemented the cleanest production technology available and installed dedicated wastewater treatment plants. These operate all year round as an integral part of DSP's manufacturing process at Delft and all other sites, in combination with the testing of effluents for antimicrobial activity. In response to the threat of antimicrobial resistance (AMR), the company is committed to minimizing the release of antimicrobial active ingredients into the environment.

In addition to improving its own production processes, DSP actively collaborates with industry partners, public and private stakeholders, associations, health professionals and regulators – such as the United Nations, World Health Organization, Access to Medicines Foundation and PSCI - to clean up the supply chains. The company has been one of the driving forces in establishing the United Nations Industry Roadmap for Progress on Combating AMR, signed by 13 leading pharmaceutical companies in September 2016, and particularly underwrites the commitment to reduce the impact that the production of antibiotics has on the environment.

In the same year, DSP celebrated the significant milestone of 15 years of green production of 7-ADCA at its Delft site, which has resulted in more than 2.5 billion cephalosporin patient treatments while significantly reducing CO_2 emissions, as well as preventing the release of antimicrobial active ingredients into the environment.

Frans Vlaar, Business Unit Director Europe America at DSP said: "Our sustainable and environmentally friendly manufacturing process not only results in a higher 7-ADCA product quality and significant reduction of the product carbon footprint, but also prevents unnecessary active antimicrobial discharge. It is highly encouraging to see that our customers increasingly recognize these benefits linked to our 7-ADCA product and manufacturing process. Thanks to the state-of-the-art techniques and processes that we apply and continuously develop further, we are able to maintain our strong position in this highly competitive industry."

DSM Sinochem Pharmaceuticals Netherlands B.V. NL 2613 AX Delft

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Dear subscribers,

in this edition we have again gathered a lot of cleanroom news, trends and products which we hope are interesting for you. There is one breaking news, however, that we would like to pass on to you as a call-to-action right here: This year, as every two years, the Fraunhofer Clean Technology Prize CLEAN! will be awarded, which recognizes pioneering developments in cleanroom technology. Take advantage of this opportunity and present your innovation for clean production environments to a distinguished panel of experts. With some luck you might be rewarded the CLEAN!-prize on stage of LOUNGES fair in Karlsruhe in February. Application period starts today and closing date for submissions is 17. November. We`re keeping our fingers crossed.

Yours sincerely,

Reinhold Schuster

Safe handling of oncology drugs made easier with Tyvek® single-use cleanroom apparel

Cytostatic drugs thanks to their healing power of destroying cancer cells can be lifesaving for patients, but may also harm healthy cells of those involved in their handling. Three protective clothing ranges - Tyvek® IsoClean®, Tyvek® and Tychem® not only provide confidence for people involved in cancer treatments, but also protect cytostatic substances from contamination, to ensure the highest quality of drugs administered to patients.

Without proper protection, cytostatic compounds represent a significant health risk as they can lead to abnormal formation of cells in healthy organisms, therefore are carcinogenic, mutagenic and reprotoxic. The greatest hazards arise by contact with cytostatic dusts, liquids or through aerosol formation. In the spirit of prevention being the best type of protection, every person handling cytostatic substances, under law must be provided with appropriate technical and organisational measures and suitable CE certified personal protective equipment (PPE). The Quality Standard for the Oncology Pharmacy Service written by the European Society of Oncological Pharmacy states: "The directives, regulations and guidelines currently in use stipulate the use of protective equipment byevery employee of a cytostatic department deriving from evaluation of the hazard involved. The PPE must carry the CE mark and must be specified in writing in the hazard evaluation."

How to choose the right garment for handling oncology drugs?

When considering protective clothing for use with cytostatics it is crucial to know different fabric technologies as they often exhibit widely varying performance attributes. For example reusable textiles i.e. polyester garments are often subjected to multiple cycles of wearing, laundering and sterilization that can impact negatively barrier properties and durability during the garment life cycle. Reusable polyester cleanroom clothing is typically not certified as personal protective equipment according to Directive 89/686/EEC.

On the other hand, Tyvek® material due to its unique versatile structure provides an abrasion resistant barrier. It provides a high level of protection against airborne particles >1µm and against permeation of a range of low concentrated inorganic water-based chemicals. Tyvek® garments are low-linting and have a smooth surface which provides very little foothold for particle adhesion. Tyvek® material is soft, and supple making garments much more comfortable to wear than other products.

Protective suits made of Tyvek® are also suitable for activities involved in the production of cytostatics and offer different levels of protection depending on hazard type. (Photo: DuPont)

Evaluation of permeation data as a part of the risk assesment

Hazard evaluation and understanding all requirements associated with a specific application are essential to determine the most effective personal protective solution. Apart from protecting people, the products must also be protected from contamination by people, e.g. by skin particles, hair, lint or other particles originating from clothing. Product integrity and the relevant aseptic procedures and GMP guidelines bear the same weight as personal protective equipment.

PPE must be provided with appropriate technical documentation proving clothing performance properties e.g. permeation data to cytostatics. In order to provide appropriate protection against a specific chemical, the chemical permeation data needs to be consulted as knowing the toxicity or consequences of short- or long-term exposure to a hazard is essential. A permeation rate indicates the mass of the chemical in micrograms (µg), which can be transferred through one square centimetre (cm^2) of the fabric in one minute (min). For further information on permeation data of Tyvek® garments please visit www.safespec.dupont.co.uk.

DuPont protective clothing - solution for every need

As single-use protective clothing, Tyvek® IsoClean®, Tyvek® and Tychem® ranges of products have the advantage that uncontaminated virgin material with a proven and documented barrier protection provided for each use.

Tyvek® IsoClean® coveralls are designed especially for use in cleanrooms and controlled environments demanding high levels of microbiological protection. Additionally, with a bacterial filtration efficiency of > 98%, Tyvek® IsoClean® coveralls offer the ability to filter out bacteria.

Protective suits made of Tyvek® are also suitable for activities involved in the production of cytostatics and offer different levels of protection depending on hazard type. Moreover, CE certified Tyvek® coveralls are available as Cat. III PPE. Accessories made of Tychem® C provide additional protection from inorganic chemicals for body parts subjected to high levels of exposure.

DuPont Protection Technologies
2984 Contern Luxemburg

New test method developed for hand disinfection

Every year World Hand Hygiene Day on 5 May reminds us how important effective hand disinfection is to prevent infection. Hohenstein Institut für Textilinnovation gGmbH joined forces with Labor Dr. Merk & Kollegen GmbH to focus on the issue of hand disinfection on a project under the ZIM programme (Central Innovation Programme for SMEs). The aim of this project was to develop a new model for testing hand disinfectants under realistic conditions of use.

By simulating the rubbing process adopted with hand disinfectants, the new hand hygiene model makes it possible to obtain results which correlate with data from tests performed on human subjects. New disinfectants can now be screened under realistic conditions, so saving costs and eliminating potential risk to test subjects. With the model it is also possible to perform comparative studies for different formulations of a disinfectant using a method that is fast and does not waste resources.

It not only allows the bactericidal effect to be established, but above all the efficacy of disinfectants against viruses through practical testing. These tests involve the use of a synthetic skin whose properties correspond to those of human skin in terms of pH value, topography, fat content and moisture management. The scientists at Hohenstein have also optimised the synthetic skin so that it can be used as a substitute for the hands of human test subjects.

A further result of the project is the development of a motorised simulator equipped with a pivoting arm. The synthetic skin can be secured at the point of contact between the arm and base. Rotation of the arm over the surface and the selected pressure setting successfully simulates a rubbing action that resembles the motion of hand rubbing during disinfection.

The scientists at Labor Dr. Merk & Kollegen GmbH performed virological tests using both the new model and human subjects and acquired data on the effectiveness of a number of commercially available disinfectants against noro, vaccinia and adeno viruses. The results of the tests performed on human subjects correlated with those for testing with the hand disinfection model.

In the course of the project scientists from both companies were also able to simulate and evaluate practical transmission scenarios. Chains of infection (e.g hand - door handle - hand) were reproduced with a stamp model using the synthetic skin or various metal plates. This was followed by analysis of the results. This demonstrated how important thorough hand disinfection is to interrupt the simulated chain of infection.

It is of great importance for medical facilities to prevent nosocomial infections, i.e. those acquired at hospitals or care homes, and specifically to avoid viral diseases. Viral diseases are often extremely contagious and spread like wildfire among patients. Disinfection of the hands, above all by staff and visitors, is an effective means of interrupting the chain of infection, so reducing the transmission of viruses. It is critical here to find the appropriate hand disinfectant.

To be categorised as being effective against viruses and authorised for use by medical facilities, a disinfectant must be listed by the VAH association (Association for Applied Hygiene) or the Robert-Koch Institute. To obtain such a listing for a hand disinfectant, the manufacturer must submit expert reports documenting its effectiveness, whereby this needs to have been ascertained by means of quantitative suspension testing. However, these tests are not designed to map the disinfecting effect in practical application. The tests performed to date on human subjects are in contrast costly and always entail a risk of infection for the test person. They are however essential to assess actual disinfecting performance. With this background the new hand disinfection model represents a realistic test method that does not require the involvement of human subjects to establish the effectiveness of hand disinfectants under realistic conditions.

Hohenstein Laboratories GmbH & Co. KG
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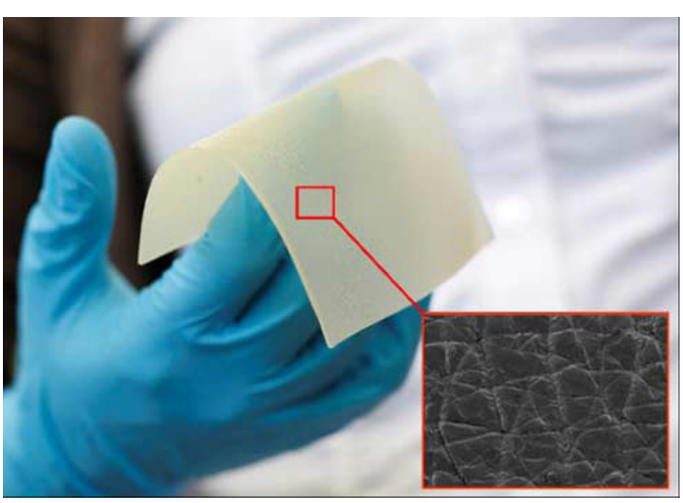
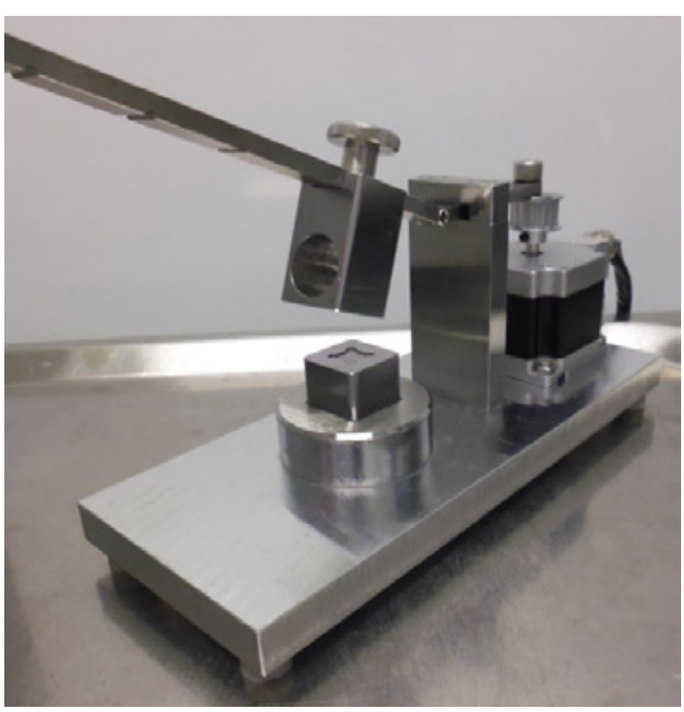


The synthetic skin material has been optimised so that it can be used as a substitute for the hands of human test subjects. (©Hohenstein Group)



The new test device makes it possible to simulate hand rubbing action in a realistic manner. (©Labor Dr. Merck & Kollegen)

Medical Moulding Company takes advantage of the full package from Connect 2 Cleanrooms

Following the installation of their ISO Class 7 modular cleanroom in September 2013, supplied by Connect 2 Cleanrooms, Amies Innovation has continued to benefit from the cleanroom validation and consumable aspects of the business.

W.E. Amies was established in 1929 as a moulding company. In 2011 they launched their sister company, Amies Innovation, to allow them to focus exclusively on the requirements of their medical technology customers. Amies Innovation manufacture injection moulded components for use in non-invasive detection, measurement and monitoring tests. Typical applications include parts and assemblies for point of care testing (POCT), screening for MRSA, drug abuse and monitoring blood coagulation for anticoagulant users.

In 2013 they were approached by IMI Norgren regarding a new project. One pre-requisite for the project was that Amies Innovation had to achieve the accreditation ISO 13485 and operations were to be carried out within a cleanroom. At the time they agreed that if they were to win the tender for the project they would install a cleanroom at their premises in Derbyshire. To win the contract they began to research cleanroom companies.

Following a recommendation from Amies Innovations moulding machinery supplier, Connect 2 Cleanrooms were identified as the preferred cleanroom supplier. They designed, manufactured and installed a modular hardwall panel system with a softwall entrance at their premises in Chesterfield covering 25.5m². The cleanroom, which has been designed to achieve 96 air changes per hour, includes the ECO 1 System allowing the operators to constantly monitor the cleanroom by recording the temperature, humidity, filter pressure and particle counts. Branding applied to the external hardwall panels personalise the room and add to appeal of the design and the transfer hatch ensures contamination free transfer of tooling equipment.

The modular cleanroom option was the ideal choice for Amies Innovation, due to IMI Norgren being a new project and their first requirement for cleanroom operations, as it allows them to expand or relocate their cleanroom at a later date based on the businesses capacity requirements.

Bob Ball, MD at Amies Innovation, praised the services of Connect 2 Cleanrooms 'The installation of our cleanroom has not only increased our sales but has also improved our credibility within the medical sector. It has been fully operational for 3 years and we are now looking to expand the room to house additional machinery due to the manufacturing demand.'

Today, Amies Innovation continues to benefit from the after-care service from Connect 2 Cleanrooms and their consumables division, Cleanroomshop.com. As part of the after-care service, Amies takes advantage of the yearly validation service as part of their service contract, which ensures the cleanroom solution continues to work at the efficiency required by Amies Innovation.

Cleanrooms

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Highly flexible system for a broad range of processes

Bosch launches a pilot fermenter for manufacturing APIs

– System can process batch sizes ranging from eight to 50 liters
– High-precision dosing of liquid process media with syringe pumps
– Fermenter offers both batch and continuous manufacturing

Bosch has launched a new pilot fermenter for the cultivation of active pharmaceutical ingredients (APIs) on laboratory and pilot scale. "In the pharmaceutical industry, the manufacture of complex compounds using biotechnological methods continues to grow in importance. Whether the desired substance is an insulin preparation or a medication for targeted cancer therapy – our bioprocessing systems deliver optimum product quality and excellent process results," says Dr. John Medina, sales director at the Bosch subsidiary Pharmatec. "With the new pilot fermenter, Bosch has rolled out a modular, fully automatic system that is suitable for R&D applications, clinical studies in the lab, and industrial production of small batches." The pilot fermenter was presented at interpack 2017 in Duesseldorf.

Modular process system for diverse cell cultures

When it comes to designing fermentation systems, the goal is to create optimal growing conditions for microorganisms such as cells and bacteria. At the same time, these systems have to meet the strict cGMP regulation standards for the pharmaceutical industry. Bosch's highly versatile pilot fermenter satisfies the specific requirements for the production of APIs, and for a diverse range of applications.

"Thanks to its modular design, the bioreactor is well suited to various cultivation processes and cell cultures. Interchangeable mixing and dosing technologies ensure that the optimal fermentation process can be found to match the customers' needs," explains Medina. Depending on the selected mixer, the fermenter can process batch sizes from eight or 13 liters, up to 50 liters. In addition, reactor sizes for 100 and 200 liters are available for pilot and small industrial batches. Bosch has complemented its existing portfolio of fermentation devices, which had previously offered production volumes ranging from 500 to 5,000 liters.

Interchangeable mixing technologies

Depending on requirements, the system can be equipped with one of several interchangeable mixing elements, designed for different cell types and process controls. The mixer regulates the inflow of liquids or gases needed for cell cultivation. Sensitive cells require the use of gentler technologies like the air lift module, while more robust cells can be stirred mechanically.

The feeding of process media takes place fully automatically. As an alternative to the installed peristaltic pumps and two additional pumps in the periphery, at the show Bosch highlighted a separate module that offers high-precision dosing for liquid media with four syringe pumps. Further, the system periphery can be expanded to include additional peristaltic pumps, so that additional process fluids can be dosed.

Continuous process controls

Since the pilot fermenter is equipped with a gentle rotary pump and a second reactor vessel, it supports batch and fed-batch processes, as well as perfusion and continuous processing. Whereas the cell culture is essentially left to itself in batch processes, fed-batch processes continue to supply nutrient solutions during fermentation, resulting in higher cell density and product yield. In turn, perfusion is suited for the highest possible cell density: the fermenter is continuously supplied with fresh media, and equal amounts of waste media are extracted from the cultivation process by the system's two hollow fiber modules.

In addition, the system is built as a package unit and the integrated wall allows the clear separation of technical section from operational area. The fermenter is designed for easy cleaning and sterilization (CIP/SIP). Its integrated periphery includes a steam generator, exhaust air cooler, and a heating/cooling device for the bioreactor. Depending on the task-specific requirements, up to four interchangeable process sensors are available. This concept enables quick installation at available spaces with limited media availability and quick changeover. Further, in terms of subsequent downstream processes and the formulation of the final injectable liquid, Bosch offers comprehensive solutions that can be seamlessly combined with other Bosch products for the filling and packaging of liquid pharmaceuticals.

Pilot fermenter for manufacturing biopharmaceutical APIs: The modular, fully automatic pilot fermenter from Bosch is suitable for R&D applications, clinical studies in the lab, and industrial production of small batches. (Picture: Bosch)

Batch production and continuous processing: The equipment of the pilot fermenter allows for batch and fed batch processes, as well as perfusion and continuous processing. (Picture: Bosch)

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At "Laser World of Photonics" trade show and accompanying "CLEO Europe" conference, the FBH presented its capability in diode lasers and UV LEDs, each device opti-mized to fit the respective application.

Extremely versatile – FBH offers tailored diode lasers, from the chip to the system

The Ferdinand-Braun-Institut (FBH) presented novel developments and advances of its diode lasers and UV light-emitting diodes (LEDs) at the "Laser World of Photonics". The event was hosted in Munich from June 26 – 29, 2017. FBH offers the full value chain in house: from design through chips to modules, and increasingly develops these devices for use as operational systems. At the booth, FBH showcased, among others, a unique, computer-controlled picosecond light source delivering high-precision pulses in the pico- and nanosecond range, a 6 kW fiber-coupled pump module for solid-state laser systems, and a demonstrator module equipped with UV-C LEDs for water disinfection purposes. The LEDs utilized have been developed within the "Advanced UV for Life" consortium that is managed by the FBH and also exhibited at the stand.

Flexible all-in-one pulse light source PLS 1030

With its PLS series, FBH offers unique laser sources that deliver high-precision pulses in the pico- and nanosecond range with nanojoule energies. Pulse energy, width, and spacing as well as repetition frequencies can be flexibly adjusted. The laser system offers freely selectable repetition rates from the hertz to the megahertz range and peak pulse powers of up to 50 watt. It uses tailored diode lasers for impulse generation combined with optimized RF components as electronic drivers – both are core competencies of the institute. The computer-controlled all-in-one system can be switched into different pulse modes and thus be integrated into various laser systems at low effort. The system is equipped with 1030 nm diode lasers, but can be easily adapted to other wavelengths. It is therefore suited for applications like material processing, bio-medical examinations, and mobile LIDAR systems. PLS 1030 was constructed jointly by laser and RF circuit experts with engineers from the in-house Prototype Engineering Lab, an FBH team that develops industry-ready and user-friendly prototypes. This way, companies get direct access to the latest state-of-art research results.

Efficient diode lasers for applications with kilowatt-class output powers

The institute develops high-brilliance diode lasers in a great variety of designs in the wave-length range from 630 nm to 1180 nm. All FBH activities aim at steadily increasing efficiency, reliability, and output power of its diode lasers and bars. In recent work, laser bars with 6 mm long resonator and 10 mm aperture have reached output powers of 1 kW, whilst maintaining an excellent conversion efficiency of 63%. Detailed results for these bars are presented at "CLEO Europe". Bars with long cavities of this kind provide ultra-low thermal and electrical resistances. They are therefore anticipated to be highly beneficial for kW-level CW operation and thus particularly attractive for industrial and scientific high-power applications. For example, such diode laser bars are used as pump sources for solid-state and fiber lasers or employed directly in material processing.

Innovations from the FBH regarding chip design and technology along with mounting and module design have enabled, at the same time, advances in pumping of solid-state systems. To this end, novel chips with a very broad aperture of 1.2 mm were integrated into innovative side-cooled stacks that are particularly suitable for pulsed operation with a larger duty cycle of 20%. The high-intensity output of the single emitters in the stacks is optically combined into a beam and then coupled with low losses into a fiber. In this way, a pump laser system is available for the first time that simultaneously offers high power, good efficiency, and a long duty cycle. Novel high energy class solid-state lasers can therefore be efficiently pumped with these systems. FBH presented an exemplary pump laser module with 6 kW peak power and an electro-optical efficiency of 50% at the booth.

High-brilliance tapered lasers with further increased output power

Tapered lasers deliver high optical output powers in a narrow spectral line with equally excellent beam quality. The FBH recently succeeded in further enhancing their output power in the spectral range between 980 nm to 1120 nm. The newly developed 1030 nm tapered diode lasers yield up to 10.3 W diffraction-limited output power, much increased to the previous record of 8 W. This corresponds to 76% of the emitted light output. This improvement was due to further optimization of the lateral spatial mode filtering and the internal wavelength-selective gratings. The latter ensure laser emission within 22 pm spectral width over the full operating range. Hence these diode lasers are also suitable for challenging applications like non-linear frequency conversion.

Ferdinand-Braun-Institut
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Vaisala launches a completely new probe for the measurement of hydrogen peroxide

Vaisala expands into a new area of measurement by launching the HPP272 probe for the measurement of vaporized hydrogen peroxide. The HPP272 achieves accurate and exceptionally repeatable measurements.

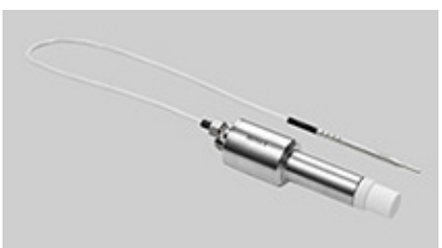
Hydrogen peroxide is used extensively in the bio-decontamination and sterilization of rooms, facilities, and equipment in the pharmaceutical industry and healthcare. For example, isolators, treatment rooms in hospitals, ambulances, or even aircraft can be cleansed with hydrogen peroxide. The need for more pharmaceutics and treatment facilities is growing in the world, and the need for bio-decontamination and sterilization grows at the same pace.

„The repeatability of measurements is extremely important to achieve reliable verification of the bio-decontamination process cycle after cycle," says Sanna Lehtinen, Product Manager at Vaisala.

Hydrogen peroxide is growing in popularity, as it destroys even the most resistant microorganisms, like bacterial spores, mycobacteria, and viruses at room temperature and low concentrations. It has no toxic by-products and leaves no residue.

One HPP probe can measure not only the hydrogen peroxide content (ppm) of bio-decontamination but also temperature, relative humidity (RH, only water vapor), and relative saturation (RS, whole gas mixture).

The probe uses the new PEROXCAP® sensor developed by Vaisala in the measurement of hydrogen peroxide; it is based on the company's relative humidity sensor HUMICAP®, which is known for its accuracy, repeatability, and stability, and it brings these qualities now to the measurement of hydrogen peroxide.



The reliability of PEROXCAP also depends on its intelligent measurement algorithm and heating function, which ensures water cannot condense on the sensor. This keeps measurement data reliable even in extremely high humidities.

Moreover, the sensor has a purge function that helps maintain measurement accuracy between calibrations and extends the operating life of the probe. This function heats the sensor rapidly to remove possible impurities left in the sensor's polymer films.

The HPP270 probes require calibration only once a year, and as very durable devices, they require very little maintenance.

The small probe has been made from carefully chosen materials. It is easy to install, and it does not require any special setup, such as a pump, to work.

The probes are compatible with Vaisala's Indigo200 series transmitters.

Vaisala's new Indigo 202: easy-to-use transmitter for smart probes

Vaisala launches a new, digital transmitter to be used with Vaisala's smart probes. The Indigo 202 provides an easy-to-use interface to different exchangeable probes.

The Indigo 202 is a new product in the Indigo series, which extends the range of Vaisala's Indigo-compatible probes. With an analog output version already on the market, now the Indigo 202 has a digital Modbus RTU output. These devices can be used with intelligent GMP251 and GMP252 carbon dioxide probes; the range of probes will be expanded going forward. The next new Indigo-compatible probe will be the HPP272 probe for vaporized hydrogen peroxide, humidity, and temperature measurement, scheduled for availability in the fall of 2017.

The GMP251 and GMP252 carbon dioxide probes are designed for harsh and humid environments. They are used in life science incubators, greenhouses, cold storages, and in demanding HVAC applications, such as livestock buildings.

One growing area of applying carbon dioxide measurements is the use of carbon dioxide in cooling and refrigeration systems, as carbon dioxide is more environmentally friendly than traditional, for example, Freon-based refrigerants.

„In these systems, the reliable measurement of carbon dioxide levels is important to ensure their safety to people," says Maria Uusimaa, Product Manager at Vaisala.

The new HPP272 probe for the measurement of vaporized hydrogen peroxide is accurate and exceptionally repeatable. Hydrogen peroxide is used extensively in the bio-decontamination of rooms, facilities, and equipment as well as sterilization applications in the pharmaceutical industry and healthcare. For example, isolators, treatment rooms in hospitals, ambulances, or even airplanes can be decontaminated with vaporized hydrogen peroxide.

The Indigo 200 series transmitters are intended for demanding conditions, as they are resistant to dust and most chemicals, and their smooth surface is easy to clean.

The transmitter has a wireless user interface for e.g. smartphones or other smart devices. Through this interface, it is possible to configure the transmitter's two relays, set the Modbus address, or change the display settings, among other things.

The Indigo 202 also helps to minimize downtime, as probes attached to it can be disconnected and changed into new ones, if needed. Instead of changing the probe, it can also be calibrated on site through the Indigo user interface, provided there is a calibration reference or a reference device available.

VAISALA

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Sumitomo (SHI) Demag presents new injection moulding machine

The new all-electric IntElect: More compact, more dynamic, more precise and more efficient

Sumitomo (SHI) Demag Plastics Machinery GmbH of Schwaig near Nuremberg presents the new "IntElect", a completely new generation of all-electric injection moulding machines. Developed in cooperation with its parent corporation Sumitomo Heavy Industries (SHI) and powered by a brand-new generation of highly dynamic drive motors, the new IntElect combines top-level performance with an outstanding energy footprint. Constructive innovative features reduce the space requirements and improve accessibility, ergonomics and machine precision. The new IntElect was presented in all its details at the in-house fair at the manufacturer's production site in Wiehe/Germany on the 10th and 11th May. Particularly interesting for manufacturers of structural precision components and of industrial and optical parts, it significantly reduces the price difference between hydraulic and all-electric machines. The specialist's objective is to enable a ROI in less than one year for all-electric applications while providing the complete range of options.

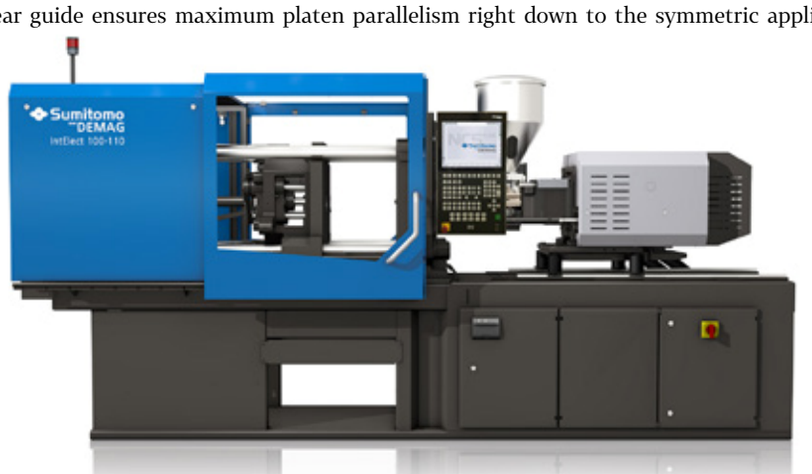
Following the successful demonstration of 500 kN model at the "K" flagship fair in October 2016 in Düsseldorf, the new and complete machine series is now available, featuring clamping forces of 500, 750, 1,000, 1,300 and 1,800 kN. An expansion of the new IntElect series both in terms of clamping force and distance between tie bars, the new 1,800 model closes the gap between large and mid-size IntElect machines. Moulders benefit from the series' extensive modular range and additional intermediate size, which provides perfectly adapted machines with up to five different screw diameters for each injection unit.

The control cabinet is integrated into the machine base of the IntElect machines, freeing up plenty of space for downstream equipment and ensuring easy access to the nozzle area and the complete clamping unit. With its new design, the IntElect has a significantly smaller footprint than its predecessors: on average, the set-up area is 10 % less than that of comparable all-electric competitors. Even the smallest model with a clamping force of 500 kN is half a metre shorter than its predecessor.

The Sumitomo corporation has already delivered more than 60,000 all-electric injection moulding machines and produced the relevant drive technology in-house. This tried-and-tested technology and the extensive practical experience accumulated over decades of manufacturing machines for moulders all over the world has been brought to bear on the latest, revised motor generation that powers the new IntElect machine series. Minimum scanning times for the injection unit, clamping unit and ejectors ensure perfect interaction of all drive train components. Included as standard, the axle controller, perfectly tuned motors, frequency converters and machine control systems deliver an outstanding drive system that is geared towards top dynamics, precision and repeatability.

Updated motor technology and extended memory capacity for brake energy provides the groundwork for a significant optimisation of all IntElect machines, resulting in 20% savings on comparable all-electric machines.

Important elements of the machine concept include sensitive mould protection and maximum mould support. In addition to this, IntElect machines offer a whole array of different options ranging from standard profile monitoring functions to mould protection force right through to ejector and injection pressure profile monitoring. The machine's top-of-the-range linear guide ensures maximum platen parallelism right down to the symmetric application of nozzle system force. A new FEM-assisted design of the platens improves production safety, while the stiffness of the moving and stationary platens was significantly increased by up to 30 %.



The new all-electric IntElect with its brand-signifying navy cladding has a significantly smaller footprint and is more dynamic, precise and efficient than its predecessors. (Photo by Sumitomo (SHI) Demag)

In addition to the standard version, the electric ejector packages are available with additional force and/or speed. The NC5 plus control system comes equipped with the new capacitive glass colour touchscreen with the improved brilliance and sharpness of a smartphone for safe, intuitive and comfortable operation.

A readily spotted signifier of the global platform, the IntElect's cladding has a new navy colour, which is available as an additional standard – consistent with the Japanese machines. The optimised design of the machine surfaces ensures easy cleaning, particularly for clean-room applications.

Developing the new machine series, the manufacturer focused on cost-efficiency and a compact footprint. Thanks to the electric drives, which are manufactured in-house, specially developed and continually optimised for injection moulding machines, this machine serie's already keen price/performance range has been made even more attractive. "We aim to be truly innovative. This means that the new IntElect does not have a random price, but the price of five years of ongoing work with the objective of building a more compact, more productive and more efficient new IntElect," CEO Gerd Liebig explains. "We reduced the price gap between these all-electric and hydraulic machines and can now offer an improved machine series that delivers perfect cost-efficiency and a ROI in less than one year. The demand for the first pilot machines from our customers is very promising: they are almost sold out."

Sumitomo (SHI) Demag
D 90571 Schwaig

LUXIONA with the innovative MILS

LUXIONA Group presented at the exhibition trade fair Light Middle East Dubai for the first time the innovative MILS (Medical Intelligent Lighting System). MILS is an intelligent system based on operating rooms to illuminate through LED recessed luminaires and motorized ceiling that allows us to address precisely the light beam anywhere in the work area.

The system provides a high quality of light and frees up space greatly facilitating the work of surgeons in the operating room. It aims simply with the push of a remote control. Eliminates shadows, avoiding obstacles in the area and increases the efficiency of the operating area and energy consumption.

M.I.L.S allows to choose not only the right spot where to direct light, but also the direction from where you want to come in a very simple way: using a pointer that will never bother the surgeon's work. It also has a set of cameras that evaluate real-time lighting levels on the operating table and intelligently regulate each of the heads of the system to eliminate shadows automatically and independently.

The luminaire blends into the ceiling of the operating room by a simple installation. Being light sources recessed ceiling pose no internal heat source in the operating room because most of the heat generated by the light is ejected in the false ceiling.

The usual way of work in operating rooms requires an overhead light on the operating table and one or two additional lamps that provide oblique light to avoid shadows on the field of view. Traditional systems introduced over the area of surgery bulky items that would normally interfere with the mobility of staff of the operating room and whose handling during surgery process is cumbersome. In contrast, M.I.L.S allows clearing all the space on the operating table and simplifies the orientation system of light on the operating table, both before starting operation and during the entire work process.

M.I.L.S is a luminaire based on LED lighting technology that provides higher quality than traditional operating room lamps and minimizing infrared radiation and ultraviolet light sources. Provides a high-quality lighting with an intensity of up to 160,000 lux with high color rendering that allows a better perception and evaluation of color (CRI> 95), and more comfortable for surgeons because it allows the use of color temperatures CCT> 4500 K which minimize eye fatigue of the surgeon during the working process.

„A new era of light technology has just started with our new MILS system. Trendsetting advantages of LED lighting will be combined with state of the art controller technology." – mentions Pawel Kramarz – Managing Director Luxiona GmbH.

Benefits to the health centre or clinic Health centres need to improve their efficiency and adapt to the new rules and procedures that will gradually implemented in the health sector, and improve efficiency.

M.I.L.S allows a perfectly lit area of operations, better insulated, more functional and comfortable for the development of the activity. Improves efficiency of the health centre in functionality, maintenance and risk of infections, energy consumption and resource optimization.

LUXIONA GmbH
D 35435 Wettenberg

ISO 13485:2016 successfully implemented by CIM med GmbH

CIM med® certified according to the latest standards

Now it is official: CIM med GmbH fulfils the requirements of the new ISO 13485:2016. This makes the internationally operating manufacturer of medical-grade mounting solutions one of the first suppliers on the market who has consistently translated the stringent requirements of the new standard into their management system.

The changes of the new standard versus the previous version dated 2003 primarily affect risk management, which now includes all processes of the management system. Also, the focus is now increasingly directed towards feedback mechanisms and the more intensive monitoring of suppliers as well as outsourced processes. Furthermore, design and development requirements were refined (plans and proof of verification, validation and design transfer). Altogether, the new ISO norm takes the requirements of the 21 CFR (Code of Federal Regulations) part 820 into account to a much higher extent.

Managing Director Manuela Deverill regards the successful certification as an important quality feature for the sustainability of her company: "Currently we are a major step ahead of other suppliers on the market. We now permanently demonstrate our performance and our awareness for quality by complying with the latest standards in the development and production of our modern advanced carrier systems as well as through our highly efficient documented processes."

In principal, all mounting solutions are inspected by CIM med® for quality and functionality from development to delivery. They comply with the Medical Devices Directive 93/42/EEC and, naturally, bear the CE marking. With regard to material resistance they meet the requirements of DIN EN 60068-2-74 as well as DIN EN ISO 2409:2013 and therefore are long-term resistant to disinfectants against multi-resistant pathogens. Furthermore, the Fraunhofer Institute attests that the support arms by CIM med® can be cleaned and disinfected with wipes by "simple wipe cleaning". As a medical product risk class 1, all solutions are conform with EN 60601-1, 3rd edition.

CIM med GmbH
D 80939 München

A natural scientist and Business Administration graduate at the head of the Hohenstein Institute for Hygiene, Environment and Medicine

Dr. Timo Hammer is the new director of the WKI

Since 01.04.2017 there has been a new man at the head of theWilliam-Küster Institute (WKI) for Hygiene, Environment and Medicine – otherwise known as the Institute for Life Science at Hohenstein's Research and Service Centre. A natural scientist and Business Administration graduate, Dr. Timo Hammer has taken charge of the institute while additionally joining the Management Board of the Hohenstein Group.

Combining a love of research with expertise in economics, putting into practice the link between business and applied science: this is the role of the institute. It brings together research and service, always revolving around the application-specific problems of its clients and aiming for optimum market positioning of their textile or textile-related products.

The research scientists and developers at WKI assist industry with a huge range of issues involving biological effectiveness and safety in the interaction of their products with man and the environment. Examples of this work include odour management of clothing, insect protection – e.g. effectiveness against dust mites, moths or mosquitoes transmitting yellow fever – or antimicrobial finishes, which make a key contribution to preventing infection. Textiles are examined for their interaction with the skin, mucous membranes and skin flora of the wearer and their suitability for allergy sufferers evaluated. This is followed by further development in line with these results.

The William-Küster Institute performs numerous tests based on the relevant standards and also carries out certification, including for medical products. First and foremost however, it offers solutions tailored to each client that extend throughout the lifecycle of the product – and sometimes even beyond. This includes market-oriented development of new products until ready for the market, sound market positioning, e.g. displaying one or more of Hohenstein's prestigious quality labels, continuous quality control and the verification of marketing claims. WKI also investigates the biodegradability of textiles once they can no longer be recycled. One possible testscenario is to bury the textile in the ground for controlled biodegradation. Testing then assesses its aerobic degradation by micro-organisms to then supply a complete sustainability profile for the product.

Thanks to its extensive interdisciplinary expertise WKI is also a competent partner for all aspects of hygiene management and monitoring, both in the public and private sector. In this function the institute is responsible for the regular inspection of locations such as care homes, hospitals, swimming baths or apartment buildings.

Hohenstein Laboratories GmbH & Co. KG
D 74357 Hohenstein

In the 100th year of its history, 2016, the BMW Group ordered the 100th EcoCFlex system from Dürr Ecoclean. The anniversary specimen of the flexible robot cell forms part of a three-unit package and has received a special painting. The machines have been serving in a volume production environment at the Steyr engine plant since May 2017.

Dürr Ecoclean supplied its 100th EcoCFlex to a South German automotive manufacturer

The first EcoCFlex machine for cleaning and deburring engine components went into service at the BMW Group in 2005. Eleven years later, when the company was celebrating the 100th anniversary of its foundation, BMW ordered the 100th cleaning machine of this type as part of a major order. Representing the third generation of Dürr Ecoclean's flexible robotized cells, this anniversary specimen was launched in production at the Steyr engine plant in early May 2017 along with two other EcoCFlex 3L systems. These cleaning machines are adapted to BMW's latest specifications for technical cleanliness, replacing the transfer systems previously employed on a production line for petrol engines.

Along with the special painting specified to suit the occasion, the BMW Group opted to order the new EcoCFlex 3L systems with handling technology comprising the Scara manipulator developed by Dürr Ecoclean. This rugged robot was purpose-designed for use in cleaning machines and convinces, among other features, with its innovative control approach. Instead of the separate robot control unit commonly adopted, the EcoCFlex 3L relies on just one single CNC controller to operate both the Scara manipulator and the cleaning machine. This simplifies and accelerates programming, service and maintenance of the overall installation. However, the EcoCFlex 3L sets new standards not only for cleaning quality and ease of operation, but also in terms of energy efficiency.

Dürr Ecoclean GmbH
D 70794 Filderstadt

Die mit einer Sonderlackierung versehene 100ste EcoCFlex wird bei der BMW Group im Motorenwerk Steyr in einer Fertigungslinie für Benzinmotoren eingesetzt. (Foto: Dürr Ecoclean)

Michael Ratigan has been appointed Vice President of Global Sales

Phillips-Medisize appoints Michael Ratigan

Phillips-Medisize, a Molex company, announced today the appointment of Michael Ratigan to Vice President of Global Sales. With the company's continued growth in biopharma drug delivery devices, consumable diagnostics, and medical devices, this is the latest in a series of strategic hires.

"Mike's leadership and experience on our team will help accelerate our growth in our targeted market areas. Throughout his career he has demonstrated strong commercial leadership skills in three mature publicly traded companies. He is a seasoned executive with a proven track record in business-to-business models serving the life science markets of medical devices, biopharmaceuticals and pharmaceuticals," remarked Matt Jennings, Chairman and CEO of Phillips-Medisize.

Ratigan comes to Phillips-Medisize with over 25 years of experience in the healthcare and life sciences space. He has spent the past six years at Unilife Corporation as Senior VP and Chief Commercial Officer. Ratigan began his career at Merck and Company, with successful assignments at Stryker Orthopedics and Becton Dickinson medical pharmaceutical systems business. Mike lived in Germany for seven years where he was a founding member of two biotechnology drug discovery companies. Ratigan has experience across a number of leadership roles including sales, marketing, business development, strategy and general management.

"It is an honor to join such an experienced and successful team. After a series of acquisitions in 2016, Phillips-Medisize has unlimited potential to deliver for the life science markets of biopharmaceuticals, medical devices and consumable diagnostics. I look forward to working together with the Phillips-Medisize, Molex and Medicom teams to add value and achieve business growth in the near and long-term," commented Mr. Ratigan.

Phillips-Medisize Corporation
D 8309 Nürensdorf

Vetter, a leading and innovative provider of aseptic prefilled drug delivery systems and Microdermics Inc., a Vancouver-based medical device company developing a novel hollow, metal microneedle drug and vaccine delivery system, today announced that they have entered into a strategic cooperation agreement.

Vetter and Microdermics Enter into a Strategic Cooperation Agreement to Develop Innovative Microneedle Drug Delivery Systems

The market in novel alternatives to needle injections is forecasted to grow rapidly, reaching in excess of 480 million units by 2030 (Roots Analysis report). Microneedles are a novel technology that can offer promising advantages as an alternative to classical needle injections and other routes of administration, mainly in reducing the injectable dose needed to trigger an immune response and accelerating drug absorption by the body. The roadblocks to commercialization are mainly due to limited investment in scalable aseptic manufacture at the later phases of development. To overcome this hurdle the two companies have joined forces to lever the expertise of both firms and enable late stage process development and device manufacture on a commercial scale. Microdermics microneedle technology is commercially scalable and capable of pain-free injections into the pharmacokinetically beneficial intradermal space, providing improved comfort and treatment to patients. Microdermics has successfully demonstrated the initial safety of its microneedle system, and is planning Phase 1 human clinical trials for vaccine and therapeutic delivery, to be initiated in 2017.

Vetter and Microdermics join forces for innovation in drug delivery. From left to right: Dr. Claus Feussner, Senior Vice President Vetter Development Service; Prof. Boris Stoeber, Co-founder and Chief Technical Officer; Grant Campany, President & CEO (both Microdermics); and Dr. David Brett, Team Leader Product and Service Management at Vetter. (Picture source: Vetter Pharma International GmbH / Microdermics Inc.)

As a leading contract development and manufacturing organization (CDMO), Vetter offers its customers a beneficial service through a combination of device development and associated drug product manufacturing and packaging services. Vetter tries to integrate its customers in technological advancements as early as possible. By continuously participating in market development in innovative and proactive ways, the company is committed to acting with the goal of increasing patient convenience and compliance in mind.

Microdermics has developed a novel commercially scalable, low-cost, customizable, metal, hollow, microneedle platform that provides efficient delivery of vaccines and biologics – addressing the global reliance on the 160-year old hypodermic needle and the economic and health implications associated with widespread needle phobia. The company's Phase 1 clinical trials to validate the effectiveness and reliability of intradermal delivery are expected to initiate in 2017. Microdermics will focus product development and clinical activities on new delivery methods for existing commercial products, providing innovative methods for partners to differentiate via a novel intradermal delivery system, as well as pursue product life cycle extensions.

"We are very happy to enter into this agreement with Microdermics, and we are excited by the initial experience of cooperation and entrepreneurial spirit we have established with key individuals at this company," said Dr. Claus Feussner, Vetter's Senior Vice President Development Service. "We believe that microneedles are a particularly innovative technology and may prove to be a promising future alternative for selected areas of drug delivery."

"Microdermics is extremely excited to work with a world-class partner like Vetter, since our strategic interests align and their decades of experience and innovation in the fill and finish segment will enable us to accelerate our commercialization strategy. Vetter's vast experience with a wide variety of drug substances provides us with an invaluable opportunity for a successful development path for our microneedle drug delivery technology," said Grant Campany, President & CEO of Microdermics. "While our individual companies differ in size, experience and structure, we are fully aligned in our vision to achieve the best possible patient convenience with our product offerings," said Prof. Boris Stoeber, Microdermics' Co-founder and Chief Technology Officer.

Vetter Pharma International GmbH
D 88212 Ravensburg

CPhI China 2017: **Gerresheimer boosts its presence in Asia and unveils new packaging solutions**

– First-ever metal-free syringe
– Injection vials from the expert
– Glass and plastic primary packaging

The Asian market is a key priority for Gerresheimer. With a total of seven production sites in China and India, the company boasts an excellent basis for manufacturing pharmaceutical packaging from glass and plastic. Products such as inhalers, injection pens, and its new metal-free glass syringe are just as much part of its range as glass vials, ampoules, and cartridges or a wide selection of plastic medicine containers.

An Asian debut at CPhI China for the metal-free syringe

Traces of tungsten or other metals can occasionally remain in the drilled hole when the cone of a syringe is molded, which can cause a problem when they are used. There is therefore a need for pre-fillable syringe systems that ideally exclude the risk of metal contaminants, particularly for drugs based on bioengineered active substances. Gerresheimer has responded to this call by developing an innovative, patent-pending man-ufacturing technology and getting its 1 ml long Luerlock Gx RTF syringe ready for series production.

Technical expertise pooled in Asia

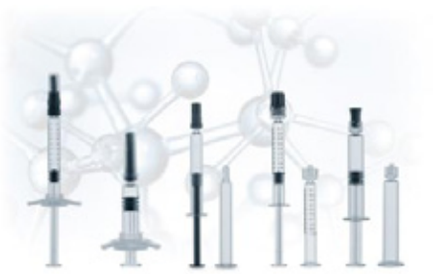
Gerresheimer opened a new development center for its medical systems made from plastic in the Chinese city of Dongguan in October 2014. Its Technical Competence Center (TCC) in China is set up to independently handle and manage large-scale projects locally. Its includes the following main departments: project management, injection-molding technology, measurement technology, tool optimization, and tool purchasing. The local project management team looks after customer projects itself, meaning no language barrier or time difference for the clients. The TCC's injection-molding team has its own sampling line complete with associated injection-molding machinery as well as its own measurement laboratory to validate its tools on site. This laboratory produces measurement reports for parts, optimizes key process parameters in order to achieve the best possible process outputs (DOE), and generates process capability indicators (Cpk analyses). The Chinese TCC is home to a highly qualified team of plastics and production engineers, project managers, quality planners, and process engineers.

The expert in injection vials

Gerresheimer's Shuangfeng site manufactures vials, ampoules, cartridges, and other specialty products made from clear and amber glass types I, II, and III for its customers, pharma companies in Asia, the U.S., and Europe. Its trade fair booth will focus on injection vials, also known simply as vials. The ones manufactured at Gerresheimer Shuangfeng can hold between 1 and 50 ml.

Glass and plastic primary packaging for medicines

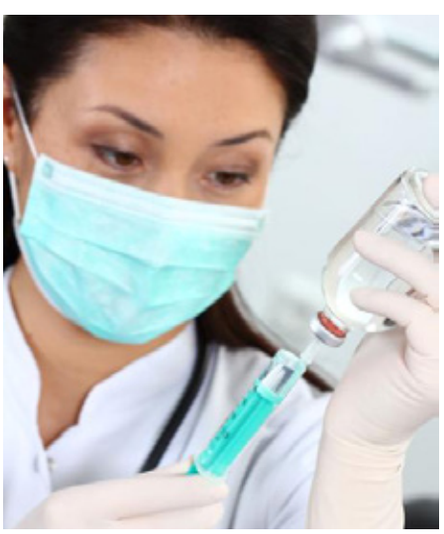
Gerresheimer has been strengthening its presence in Asia this year, opening a new production facility in the Indian city of Kosamba to make vials and ampoules for local and international customers. Gerresheimer thus now boasts three sites in India. The Neutral Glass plant in Kosamba manufactures pharmaceutical primary packaging made from container glass, while the Gerresheimer Kosamba factory next door produces vials and ampoules from tubular glass. The Triveni Polymers plant in Kundli makes plastic containers bearing the Triveni Round and Square brand name. With its Duma, Dudek, and Triveni product lines available worldwide, Gerresheimer offers a diverse range for all manner of different drugs in various forms and sizes and with various closure types.



Global ties

Gerresheimer's factories in Asia, Europe, and the Americas work closely together as part of a global network. They apply good manufacturing practice (CGMP) principles rigorously and are certified to ISO 9001 and 15378 as a bare minimum. All Gerresheimer products comply with the relevant pharmacopeias (Ph. Eur., USP, and JP).

Gerresheimer AG
D 40468 Düsseldorf



Cleanzone 2017: **Digital monitoring solutions facilitate efficient controls, traceability and fault detection**

Has the permissible particle concentration been exceeded? Is the relative humidity over the limit? Is an excessively high temperature endangering the stability of an active ingredient? In these cases, or any other time that critical conditions arise in cleanrooms, personnel can benefit from proper digital monitoring, as it makes it possible to trigger immediate alarms, obtain a comprehensive overview of the situation, react rapidly and take prompt countermeasures. Even so, it is not always easy to integrate modern processes into the analogue structures that have developed over the years at a pharmaceutical company. Seeing as cleanrooms are particularly sensitive areas in every respect, they are also in a position to be among the pioneers in the field of digital monitoring. A visit to this year's Cleanzone trade fair on Tuesday and Wednesday, 17-18 October 2017, in Frankfurt am Main, offers a glimpse of what the future holds.

In many areas of pharmaceuticals production and analysis, the advantages of comprehensively networking machines, measurement equipment and documentation systems are evident. In keeping with "Industry 4.0", modern digital solutions facilitate efficient controls, the traceability of lots and the detection of possible irregularities or faults. Yet not everything that delivers digital values is actually digital from start to finish. There are also 'semi-digital' systems, as well as physical conditions that can make it necessary to establish an interface between analogue and digital systems.

A good example is offered by the monitoring of sterile production, filling and/or packaging for pharmaceuticals, in which case the data generated is generally analogue. The key parameter is the number of airborne particles in a predefined volume of air. In industrial practice, this parameter is measured under GMP (Good Manufacturing Practice) conditions in cleanroom zones A and B continuously, while values for zone C are recorded on anything from an hourly to monthly basis, and for zone D anywhere from daily to yearly. Due to the fact that particles can be seen as potential carriers of biological contamination, the data provided by the particle counters is also fed into the risk assessment for biological contamination.

Furthermore, other factors such as the differential pressure between various cleanroom zones, and naturally also between the cleanroom and impure areas surrounding it, are also monitored continuously. The relative humidity is often another important parameter. As a general rule, it is also recommended that the temperature be monitored for any location in which medications or other products remain for more than 24 hours. Regardless of whether they are determined via a resistance measurement or by other means, the data produced are primarily analogue.

Directly after measurement: analogue is converted into digital

In traditional plants, the data are largely transmitted via analogue cables. However, the digital alternative offers significant advantages: whereas an analogue cable can only ever transmit one signal, a digital cable is able to transmit a great deal – after all, that is why it is possible to receive so many television channels today, rather than just two or three. In the field of measurement technology, this principle also makes it possible to collect large volumes of data from multiple locations and communicate it outside the cleanroom by means of a single cable (e.g. Modbus systems). At the same time, it is possible to check that the equipment is functioning properly, in order that any 'faltering' sensors can be quickly recognised and replaced, for example.

Digital transmission is also helpful when it comes to determining the reliability of the results. Just as the picture would often become distorted on the televisions of old, analogue signals in general can be disrupted by motors, other drive systems or screens. With digital transmission, on the other hand, you either receive an excellent image / clear signal, or nothing at all (= system fault).

If the data is always collected in analogue form, and data storage, including the presentation of data over time etc., is always performed in digital form, it is only natural to ask: at which point should the signal be converted? In order to minimise the possibility of disruption, it is best to convert the signal as close as possible to its source. With modern sensors it is possible to complete the entire process within two millimetres of the sensor itself – both the purely technical analogue-to-digital transformation and the conversion into the desired measurement value while accounting for the calibration data.

Will everything be wireless in future?

If we take "Industry 4.0" seriously, it should be possible to do more than simply generate the digital value directly at the sensor. We should also be able to correlate values from various sensors and even involving different parameters (particle load, temperature, relative humidity) with one another. To this end, multiple devices in the cleanroom would communicate with one another, so that warning signals could be sent to the control centre even before individual threshold values are exceeded: "Warning: while everything is still okay, the measurement values are moving towards a situation in which normal operating conditions could be breached." Is this a realistic hope?

"It is already possible for control systems to independently switch off machines when the particle concentration exceeds permissible levels. The control centre is then informed of this afterwards," explains Thomas Christen, Technical Director at vali.sys in Wetzikon, Switzerland. "Naturally it is also possible to conceive of a pool of various measurement data rather than just a single target-actual comparison. While this is rarely seen in actual practice, it is a method that holds promise for the future."

Cleanzone 2017: Digital monitoring solutions

Among the concepts put forward are systems with sensors that transmit data wirelessly to the cloud, from where any relevant alarms are triggered. For users, this means no server, no updates and access from anywhere – an entirely internet-based system. "Food producers and climate-controlled warehouses are already taking advantage of the opportunities this offers," reports Philippe Trösch, Sales Engineer for Novasina in Lachen, Switzerland. "For companies that are hesitant to take action here, be it for regulatory reasons or due to other concerns, or who do not wish to do without their existing server structure, for example, the solution is clear: extremely modular systems." Their utilisation in cleanrooms as separate, moderately-sized 'self-contained worlds' might even be particularly suitable here.

Visitors to Cleanzone will be able to transport these and other ideas to their own operations, and may even be able to begin putting them into practice the very next day – whether within the framework of advantageous concepts for a new installation or as part of a gradual integration of digital monitoring solutions into existing pharmaceutical cleanrooms.

17th - 18th October 2017: CLEANZONE 2017, Frankfurt am Main (D)

cleanzone

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Schreiner MediPharm Enhances Innovative Security Concept for Clinical Trials

New Flexi-Cap for Clinical Trial Supplies Combines First-Opening Protection with Reliable Blinding

Schreiner MediPharm has added a new version to its Flexi-Cap product family: Flexi-Cap for Clinical Trial Supplies (CTS). Flexi-Cap is an innovative security solution that irreversibly indicates the first opening of primary containers and thus prevents illegal filling and reuse of empty containers with counterfeit substances. The innovative development combines first-opening protection with reliable blinding of transparent containers used in clinical trials. Thanks to opaque-printed film caps, investigational products cannot be distinguished from each other. In addition, an integrated Booklet-Label offers ample space for product information in different languages.

Product candidates in clinical trials must be reliably blinded in order to achieve optimum test results. There may be visual differences between the active drug and the placebo, such as different colors, which must not be discernible by the trial subjects. Consequently, when transparent containers are used, the label must meet special requirements. In addition, it is important to protect clinical trial supplies against tampering. Extensive product descriptions in diverse languages are another prerequisite for clinical trials to be efficiently and flexibly conducted in an international context.

Flexi-Cap for clinical trial supplies consists of a label and two opaque-printed film caps that completely wrap around the container. While one cap encloses the lid and upper part of the container, the second cap protects its bottom and lower portions. A Booklet-Label affixes both caps to the container and offers ample space for text in several languages. The new Flexi-Cap solution thus ensures reliable blinding of transparent containers combined with irreversible first-opening protection due to a tear strip integrated into the upper cap.

Applied without heat, the solution consisting of the caps and label is suitable for temperature-sensitive substances. Flexi-Cap for clinical trial supplies can be flexibly adapted to glass containers of various types, shapes and sizes and also protects them against glass breakage. Various colors with high opacity may be used for the caps. The lid of the film cap offers additional space which may, for instance, be used for imprinting with codes or for integration of NFC chips for interactive applications.

Schreiner MediPharm
D 85764 Oberschleissheim

Switzerland's medtech industry will convene at Messe Luzern from 19 to 20 September 2017. Six reputable competence partners and around 160 exhibitors will show practical examples of how new designs, materials, technologies and processes are leading to innovations in the medical field.

The Swiss Medtech Expo makes innovations visible

19th - 20th September 2017: SWISS MEDTECH EXPO, Luzern (CH)

The second edition of the Swiss Medtech Expo will bring the decision makers of manufacturers together with leading providers and experts from the medtech supplier industry. „Again this year, we want to make the Swiss Medtech Expo the place where the exchange of knowledge and ideas for future innovative projects takes place", explains exhibition director Fabrizio Raffa.

Contribution towards promoting innovation

The application-oriented medical technology exhibition demonstrates how new technologies and applications enable innovation in the medtech industry. Six focal points demonstrating the potential for medical technology are at its centre. Each of these focal points will be presented by a reputable competence partner who will bring his entire know-how to the Swiss Medtech Expo.

Focus topic	Competence Partner
Additive Manufacturing	University of Applied Sciences Northwestern Switzerland FHNW
Plastics in Medical Technology	Swiss Plastics IG Medical
Carbon Composites	Carbon Composites Switzerland
Smart Design & Engineering	pdz ETH Zurich
Industry 4.0	Health Tech Cluster Switzerland
Innovative Surfaces	ZHAW School of Engineering

Showcases make innovations visible

The presentation of these focal points is very practice oriented and illustrative. „We want our visitors to gain inspiration and ideas for their own projects", explains exhibition director Fabrizio Raffa. „We are convinced that this is only achievable through an intensive reference to practice." Around 160 national and international exhibitors at the Swiss Medtech Expo display their skills and competencies in the form of showcases. Showcases are innovative examples of applications that the exhibitors have already launched on the market. The showcases demonstrate the innovations that can result from the intelligent combination of new materials, technologies and processes.

Innovation Symposium: lectures by competence partners

The Innovation Symposium is also dedicated to current innovations. The various competence partners will present their subject area in the symposium and highlight the potential for medical technology. Visitors from the industry can look forward to insightful expert speeches and discovering details about the showcases and the creative processes and challenges behind them.

Messe Luzern AG
CH 6005 Luzern

Phillips-Medisize corp. honored as supplier to MDEA finalist ivWatch

Phillips-Medisize congratulates ivWatch, LLC on their recent recognition as a finalist in Medical Design Excellence Awards (MDEA). ivWatch LLC is a nominee for the Model 400 device in the Nonsurgical Hospital Supplies and Equipment category. Winners will be announced on June 13, in New York, during a ceremony at MD&M East.

The ivWatch Model 400 is a device that continuously monitors a patient's peripheral IV for the early detection of infiltrations – when medication or fluid leaks outside the vein into the surrounding tissue. Intravenous therapy is a routine part of treatment for nearly 80% of patients in the U.S., and more than 20% of these IVs may fail because of infiltration. Because every IV failure risks both a serious drug delivery error and tissue damage, earlier detection of those failures is the new and next step for minimizing this potential for patient harm.

"We have partnered with ivWatch since 2011 on development and production, so it is a true privilege to be recognized as a supplier for their program. They are a great example of a company that utilized our full capabilities, from design to manufacturing," comments Matt Jennings, Chairman and CEO, Phillips-Medisize.

"Phillips-Medisize has been a valued-partner in getting the ivWatch Model 400 to market. We have leveraged their design and manufacturing expertise to solve a significant medical issue," says Gary Warren, ivWatch President & CEO. "It is a pleasure to be able to recognize the team at Phillips-Medisize as one of our honored suppliers for the MDEA Competition."

The MDEA are the medtech industry's premier design competition committed to recognizing significant achievements in medical product design and engineering that improve the quality of healthcare delivery and accessibility. The awards program celebrates the accomplishments of the medical device manufacturers, their suppliers, and the many people behind the scenes—engineers, scientists, designers, and clinicians—who are responsible for the cutting-edge products that are saving lives; improving patient healthcare; and transforming medtech—one innovation at a time.

The 2017 MDEA Juror Panel selected 45 exceptional finalists in nine medical technology product categories. Products were judged based on design and engineering innovation; function and user-related innovation; patient benefits; business benefits; and overall benefit to the healthcare system. Unlike other design competitions that are merely styling contests, the MDEA jury is comprised of a balance of practicing doctors, nurses, and technicians alongside industrial designers, engineers, manufacturers, and human factors experts.

Phillips-Medisize Corporation CH 8309 Nürensdorf

Fakuma International Trade Fair for Plastics Processing

17.10 - 21.10.2017: FAKUMA, Friedrichshafen (D)

Fakuma 2017: Full House for 25th Birthday!

The Fakuma international trade fair for plastics processing will celebrate its 25th birthday "as befits its social status" in the fall of 2017! "As befits its social status" above all because the exhibition centre in Friedrichshafen on Lake Constance will once again be fully booked out for the 2017 edition of the world's second ranking event for industrial plastics technology and plastics processing. Previously unused floor space reserves will even be occupied this year in the two foyers at the east and west entrances, in order to meet the floor space requirements of established as well as various new exhibitors, and to significantly reduce the waiting list of hopeful aspirants. But also "as befits its social status" because the more than 915,000 square feet of overall exhibition floor space will be occupied this year by roughly 1700 exhibitors from 35 countries (including Germany) – and the proportion of manufacturers and distributors from outside of Germany lies within a range of greater than 35%, thus resulting once more in growing internationalism!

The plastics industry is having to reinvent itself to a given extent!

The lasting trend towards participation at Fakuma, which is held in the technology region on Lake Constance where Germany, Austria and Switzerland meet, can also be explained by the fact that large segments of the plastics processing industry are changing – or are being forced to change – through the use of new materials, technologies and processes. 3D/4D printing technologies, as well as techniques and solutions for highly efficient processing of hybrid, composite and sandwich materials can be mentioned here as examples – above all and especially because the automobile industry and its suppliers are also making use of the opportunities offered by a broad-ranging portfolio of chemical solutions to a greater extent than ever before due to multifaceted requirements for affordable lightweight structures. The process sequence for material and resource-conserving processing of these new or alternative materials is based in turn on elementary building blocks such as new machines, adapted moulds and mould standards, integrated quality assurance systems and controllable hydraulic/pneumo-hydraulic/electric drives, as well as network-compatible and thus communication-capable controllers plus software – keyword: Industry 4.0!

Knowledge and Technology Transfer in Theory and in Practice

In actual practice, plastics processing at Fakuma includes injection moulding, extruding, thermoforming and 3D printing, as well as further processing right on up to integrated module assembly and sterile packaging under cleanroom conditions, for example of technical medical components ands assemblies. But plastics processing at Fakuma also includes beneficial theory in the form of presentations held at the highly popular, time-tested exhibitor forum which is booked out every year. Top experts present new technologies, enhanced processes, product innovations and new solutions for improved economic efficiency in the production of plastic parts at the forum in brief talks, and then place themselves at the disposal of their audience for an in-depth exchange of views. And thus by being a convincing, living example of its anniversary maxim, namely "Plastics Meets Business", and by presenting it in a practically oriented fashion, the Fakuma international trade fair for plastics processing sees itself as an innovation engine for the plastics industry once again on the occasion of the 25th edition of its successful existence.

P. E. Schall GmbH & Co. KG D 72636 Frickenhausen

Due to its short response time at low temperature the HMC03M humidity sensor is optimal for weather observation in the upper atmosphere.

Heated Humidity Sensor for Radiosondes

The HMC03M humidity sensor from E+E Elektronik is dedicated for use in radiosondes and weather balloons. The sensor is characterized by a short response time even at low temperature. An integrated heating resistor ensures an excellent measuring performance under condensation and icing conditions. This makes the sensor ideal for weather observations in the upper atmosphere.

The HMC03M combines on a silicon substrate a capacitive relative humidity (RH) sensor and a heating resistor. By heating, the sensor quickly recovers after condensation or icing, which leads to a very good measuring performance even under extreme weather conditions. Another key feature of the HMC03M is the short response time at very low temperature.

As a result, the HMC03M is ideal for use in radiosondes to measure humidity in the upper atmosphere.

The 5.85 x 2.85 mm small SMD sensor is appropriate for automatic assembling with subsequent reflow soldering. HMC03M is available on tape and reel of 500, 1000 or 2500 pcs.

Also humidity probes and transmitters for meteorology

E+E Elektronik's product range for meteorology also includes probes and transmitters for highly accurate humidity and temperature measurement. The sensing elements of these devices are well protected from pollution and corrosion by the proprietary E+E coating. This leads to improved long-term stability and a longer lifetime, two essential criteria for long-term use in weather stations.

EE33-M humidity and temperature transmitter for weather stations. (Photo: E+E Elektronik)

HMC03M heated humidity sensor for radiosondes (Photo: E+E Elektronik GmbH)

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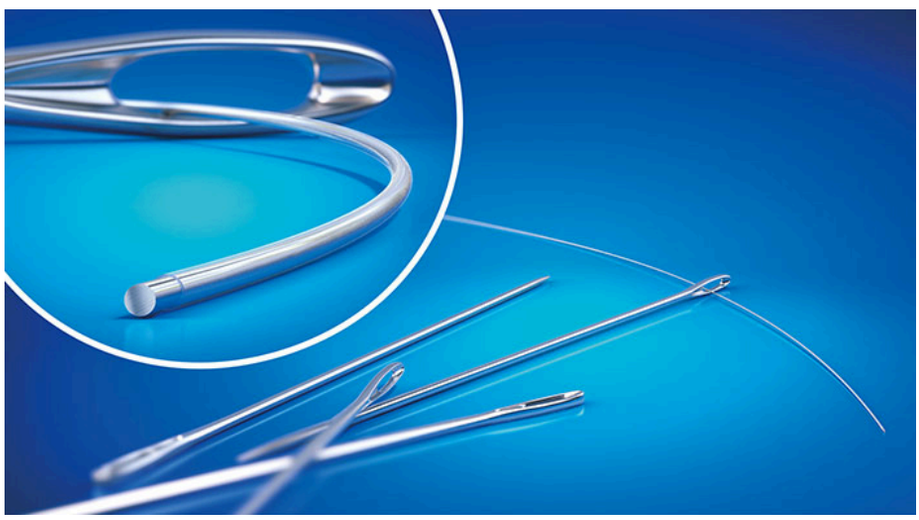
RAUMEDIC exhibited at MD&M West in Anaheim: Combining the Strength of American and German Engineering

As a polymer component system provider for the medical technology and pharmaceutical industry, RAUMEDIC was exhibiting at the MDM West show in Anaheim February 2017. The company has demonstrated its ability to implement customer ideas in products that expertly combine functionality and cost-effectiveness.

This year the themes which guided RAUMEDIC's presence at MDM West were smallest tubing as well as micro molding parts, Co-Extrusion and examples of set assemblies.



Coated Micro Cables

RAUMEDIC Competencies in Micro Extrusion and Micro Molding

The company is meeting the ongoing trend towards minimally invasive procedures with its ultra-small dimensioned tubing and molded parts, providing impressive functionality in minimal space, all manufactured to the most precise tolerances. It is part of our one overarching goal as a developer and producer of polymer solutions: procedures that are patient-friendly and ensure fast recovery.

And RAUMEDIC does not limit itself to thermoplastics and silicones. Metal components like ultra-fine wires and electronic components, combined and integrated with high-performance polymers as well, are the key features appearing today in the medical technology solutions of tomorrow.

RAUMEDIC Co-Extrusion: No Other Topic has So Many layers

Multilayer tubing offers a modern, effective and practical solution for various medical applications. Such tubing offers a design solution for medical systems that require the use of inert material solutions for drug delivery applications or bondable outer tubing layers.

RAUMEDIC has developed processing capabilities to co-extrude a wide variety of metal wires and glass fibers within the tubing walls. The company can co-extrude and work with copper, stainless steel, Nitinol, platinum alloys, nickel and silver plated wires in combination with a wide variety of polymers, including Polypropylene, Polyethylene, Nylon, Polyurethane and Silicone, as well as high performance resins (FEP, PEEK, PPSU, PEI and PTFE Moldflon™).

Within the medical device industry, many products need wires, cables and coils to be hand strung though multilumen tubing, which can be very labor intensive. With the RAUMEDIC approach of co-extruding wires within the tubing walls, fabrication costs can be significantly reduced. RAUMEDIC can offer co-extruded tubing where the wires are embedded or loose which can help with regards to kink resistance. A wide variety of wire and polymer combinations depending on the requirement can be adapted to the application requirement.

Set Assemblies – Application Example: Colpotransilluminator with Vacuum Hose

The example of the Colpotransilluminator with a vacuum hose, which is used in a gynecological application, clearly illustrates the various RAUMEDIC processing techniques. The tubing set consists of various components that are produced in multiple production steps.

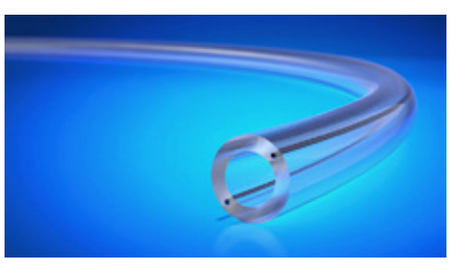
The first step is the extrusion of the tubing. In a second step tubing is cut-to-length and assembled to various connectors. A 100% bond-strength test is performed to ensure that tubing and connectors are correctly linked together.

All components are produced in-house whereby manual and customized-tool supported processing techniques such as extrusion, molding, cutting and assembly (bonding) come into play.

An easy fit connection of the Colpotransilluminator to the standardized suction port allows for ease of handling and use in the OR. With help of a minimally invasive procedure, the tubing set ensures a hygienic and residue-free suction of the wound secretion that is important for an optimal healing process.

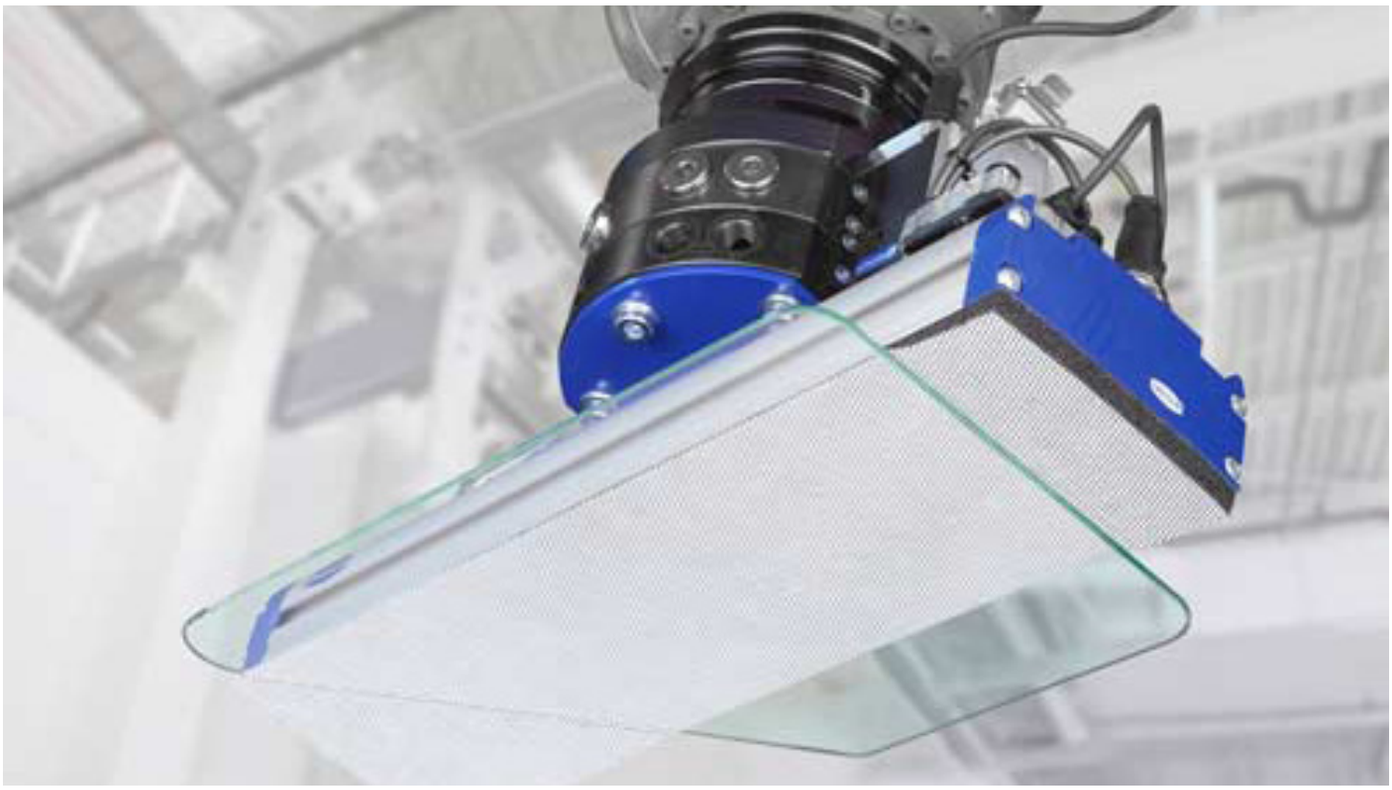
Raumedic AG
D 95233 Helmbrechts

Micro Molding



Polymer and Wire Co-Extrusion

Vacuum Hose Assembly



FXP area gripping system with protective cover for gentle handling of sensitive workpieces (Image: J. Schmalz GmbH)

Handling Sensitive Workpieces Safely

A Fine Art

The transport of goods with sensitive surfaces requires a gentle touch. With that in mind, J. Schmalz GmbH has developed a special cover for its vacuum area gripping system FXP/FMP. It can be used, for instance, to grip even very thin glass gently and without scratching. The gripping system can also use the protective cover made from a special mesh in cleanroom applications.

The integrated valve technology on the area gripping systems and the soft, adaptable sealing foam together with the small suction cells allow workpieces of different shapes and sizes to be handled gently. If operators also fit their FXP/FMP area gripping systems with the new protective cover, they can transport items like thin display glass along the entire assembly line without damaging them. Workpieces with coated and polished surfaces can also be handled without scratching them. The combination of area gripper and protective cover is also an efficient tool in the manufacture of glass sheets in the building and automotive sector. Furthermore, area gripping systems with the special mesh are certified for use in cleanroom classes 2 to 6.

The foam surface of the gripper has small vacuum chambers that evenly distribute the required suction force onto the part to be lifted. It is especially gentle on the material when combined with the special mesh. Unlike other suction processes, shearing forces due to suction cup lips standing at an angle cannot be produced while using an area gripper with foam. As a result, relative movement between the suction cup lip and the surface is avoided: The plastic does not rub against the workpiece while picking it up and therefore cannot cause abrasion. The sensitive surfaces remain undamaged.

The user benefits from a system that is easy to operate and maintain. Dirty protective covers can be replaced quickly and easily thanks to a separable adhesive bond. The pattern of holes defined on the mesh layer allows sufficient quantities of air to flow through at all times. That ensures high process reliability and the optimum adjusted surface pressure.

J. Schmalz GmbH D 72293 Glatten

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