biw COMPACT

3/2012

INNOVATION AT A GLANCE

Flexibility, opportunities, innovations

EDITORIAL

Dear friends of BIW,

We are not just concluding our 40th anniversary year with the third issue of our customer magazine but also our first year of professional, direct communication with our customers in the form of our e-newsletter and online magazine, which are both entitled "BIW COMPACT".

In this issue, we would like to once again draw your attention to the diversity of sectors in which there technically challenging uses for silicone extrusions, tubes, ready-made sealing frames, silicone mouldings, silicone coated cable protection systems and electrical insulating tubes. All BIW's products and customer-specific solutions have high levels of temperature stability and low-temperature flexibility, as well as excellent resistance to aggressive media and environmental influences.

At the end of what has generally been a turbulent year economically but for BIW a successful one overall, we would like to wish all our customers, partners and suppliers all the best for 2013.

Happy reading!

Ralf Stoffels Dr. Markus Wiethoff

INDUSTRY-SPECIFIC ACTIVITIES AT BIW DIVERSITY MAKES THE DIFFERENCE

BIW specialises in processing silicone rubber and technical textiles and also in combining the two.

This expertise, which has been accumulated over many years, has resulted in an exceptional, unparalleled range of customer-specific solutions spanning all industries. This diversity is not just demonstrated by the constantly growing number of new products but also by various activities which are designed specially for individual industries.

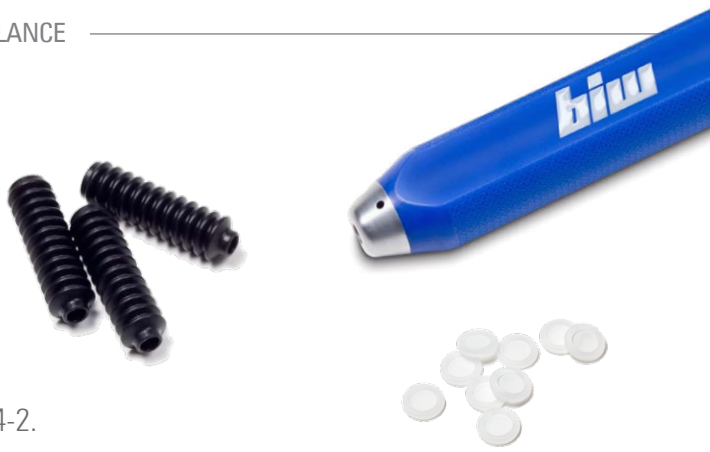
Another of BIW's strategic activities is its presence at industry-specific trade fairs. In 2012 alone, BIW experts have had their own stand at four established fairs, where they offered both existing and new customers support and advice. They were CoilTechnica in Hannover, which focuses on electric mobility and electrical isolation, Innotrans in Berlin, which concentrates on railway technology, the IZB in Wolfsburg, which revolves around the automobile industry and Aeroliance in Clermont-Ferrand, which is an aviation trade fair. In each case, visitors were impressed by BIW's general knowledge and even more so by its industry-specific expertise.

Based on use, the industries in which BIW is successful can be summarised as follows:

We recently published some industry brochures entitled "Rail", "Aviation", and "Medicine" which are available in print form. They all contain industry-specific details such as technical data or information on special approvals which are of special interest to the experts among our customers in certain industries. They answer lots of questions in a compact format and therefore provide our customers with an additional professional service.

- AUTOMOTIVE
- AVIATION
- ENERGY
- RAILWAY TECHNOLOGY
- HOUSEHOLD APPLIANCES
- SANITARY
- MEDICINE AND PHARMACEUTICALS
- HEAT PROTECTION

__ DR. MARKUS WIETHOFF



MANUFACTURING AND HANDLING SILICONE PRODUCTS UNDER CLEAN ROOM CONDITIONS

Installation of a medical cell in the moulding production area with an adjoining class 7 clean room complying with DIN EN ISO 14644-2.

Clean room

BIW also has a strategic milestone to announce concerning the new building at Pregelstraße 2 for silicone mouldings. With regard to handling products with especially sensitive properties we can now offer our customers solutions developed under clean, controlled production conditions where medical and pharmaceutical technology products and things like technical applications used in the automotive industry are manufactured and processed.

A medical cell with individual workstations and special technical equipment for manufacturing and processing challenging products had actually been erected by the middle of this year. A class 7 clean room complying with DIN EN ISO 14644-2 was also installed and connected directly to this area, which only selected people are permitted to enter.

As a result of the construction of this area, the development and implementation of special production standards will be systematically continued, as well constant improvements. In addition to mouldings all BIW's other products (e.g. silicone textile-reinforced high-pressure hoses) can also be processed, tailored and packaged in the new area.

Medical devices are only produced and certified under controlled conditions in accordance with DIN EN ISO 13485 at BIW. Along with the demand for high product quality we create trust with our management system, which is based on the principles of ISO 9001 and ISO/TS 16949. We are also certified according to ISO 14001 (environmental management system), ISO 50001 (energy management system) and IIP (Investors in People).

As a rule special materials which meet the requirements of our customers are used for medical devices. We are able to call on the many years of experience of our developers and application engineers here. The BIW Technology Centre is well staffed and equipped to meet the special and cleanliness material requirements of our medical and pharmaceutical customers.

BIW – that means special products and great expertise!

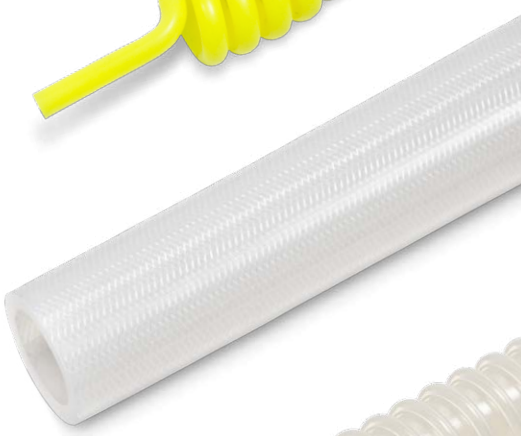
Just as they can for any other industry, silicone moulding products for the medical technology industry can be made with LSR (liquid silicone rubber) and/or HCR (high consistency rubber). The best technical and economic solution is worked out for each individual customer according to requirements and production processes.

High hygiene standards and the need for regular cleaning in the medical and clean room area are placing unusual challenges on both our employees and the technical components there, as special handling instructions, cleaning regulations, and strict work clothing rules have created a new situation for our trained employees. This means that constant support and training for our employees is absolutely essential to ensure that production always occurs under clean room conditions.

Please don't hesitate to contact us if you would like to know more about our medical applications. We can develop the perfect solution for your project too. For more information visit the BIW homepage

www.biw.de/en

__ SVEN BRAATZ



WHAT DOES "MANUFACTURING MEDICAL DEVICES" MEAN?

If silicone rubber tubes are made for medical devices, which are to be used for say dialysis equipment, there doesn't seem to be any difference to making tubes for other uses at first. However, these tubes are used on people, and this is where the difference between them and standard tubes occurs. Any production error can, in the worst case, cost a human life, and it is for this reason that extreme care is required during the manufacture of medical devices and complete traceability for each production step is important.

Those who make medical devices are therefore obliged to have a system in place which complies with EN ISO 13485 in addition to a management system based on ISO 9001. The system complying with this standard supplements the existing procedures based on ISO 9001 with extra elements which fulfil the demands for medical devices. One of these elements is the obligation to record production steps in detail and keep this information for an extended period of time, so that in the event of a legal case, any little detail, which could have resulted in a problem can be traced in a legally incontestable manner.

A risk management system complying with EN ISO 14971 is used to assess the risks arising from the intended use of medical devices. This system extends familiar procedures from automotive uses and involves looking at the risk which might remain to the patient after extreme care and compliance to all relevant standards have been applied and has to be accepted, if the use of the product is to be at all appropriate and beneficial.

Fulfilling these and other extensive requirements, which are specified by the Medical Devices Act (MPG) in Germany enables us to confirm compliance with the Medical Devices Directive ("CE mark") for relevant products and launch these products directly onto the market responsibly. This means that we aren't just a manufacturer of tubes with certain dimensions, but ultimately also responsible for any problems caused by a non-compliant product, including people who become ill as a result of them.

This is why only certain facilities, whose suitability has been checked (validated), will be used in the purpose of manufacturing medical and pharmaceutical devices. The number of people who make and monitor these products will also be limited, so that production can be kept as constant as possible and taken care of by people with many years of production experience.

Overall, the area of medical and pharmaceutical devices is a very challenging field and it certainly necessitates changes in several respects (e.g. clean room technology). But if these changes are implemented correctly it can and should also be a good example and a role model for other areas.

__ DR. HANNS-WALTER TUNGER

DR. HANNS-WALTER TUNGER INTRODUCES HIMSELF

NAME:	Dr. Hanns-Walter Tunger
POSITION:	Research & Development, Medical Device Advisor and safety officer
TITLE:	Dr. rer. nat., Graduate Industrial Chemist
TRAINING:	Degree in chemistry at the University of Hamburg, 1995 doctorate in Hamburg in liquid crystalline materials
INTERESTS:	Furniture building, model building and cooking (international cuisine)

GOALS AT BIW:
To expand the medical devices department, particularly against the background of a dynamic regulatory environment. To prepare the market launch of BIW's own silicone rubber product lines for the medical technology industry. To continue developing BIW's existing clean room technology.

IIP – SUCCESSFULLY CERTIFIED STAFF MANAGEMENT

The competence slogan included in the BIW logo "When it comes to competence", which all our employees actively represent for customers, and the demographic factor, which is making the search for suitable qualified junior staff for the next generation more and more difficult, have prompted the management to create and introduce a systematic staff management system. The project was first initiated some years ago as a process development project resulting from the Kaizen philosophy, which BIW has actually been using actively since 1995 in the form of regular workshops and continuous improvement processes (CIPs).

Now, staff development has been added to the process development measures. As there are hardly any specialists for silicone extrusion, LSR and HTV injection moulding, processing and refining technical textiles on the job market BIW has set up its own internal training and further development programme. AGSW (Arbeitgeber Südwestfalen), South Westphalia's training association for regional employer unions, has supported and moderated the expansion of the project and involved the employees in it.

Training and handling instructions systematically embedded in the management system, which has been certified several times over (ISO 9001, ISO/TS 16949, ISO 13485, ISO 14001, ISO 50001), have now been added to the process models and describe all the important production steps in clear, simple sentences, which were composed in small groups in conjunction with the employees.

Based on the management system documents, training and further development templates were created for all BIW's employees, which show them where they stand and what the next few steps in their personal development plan are.

INVESTORS IN PEOPLE

One important step in the development of this comprehensive staff management system was a certification audit, which was conducted according to the international standard IIP - Investors in People. It also served as external verification of the fact that BIW is on the right path for the future. BIW successfully passed the audit, which included a large number of individual discussions and group interviews to assess and evaluate the status of staff development, and is now proud to be an official bearer of the "Investors in People" logo.

As part of this process, a brochure entitled "Welcome to the Team - Help to Shape the Future" was published for all BIW's employees. It clearly presents

- BIW's requirements and goals
- the organisation with the process model and organigram
- the different departments and contacts for them
- the different customer sectors with product-specific applications and
- BIW's internal rules in the form of a company agreement

and therefore strengthens employees' motivation and identification with the company.

IIP certification is an important step with regard to sustainability and the further development of BIW as a competent problem solver in the international market and competition environment.

__ RALF STOFFELS

BIW WELCOMES SIX NEW TRAINEES

On 2nd September 2012, six new trainees took the first step towards their future professions. Four are training to be plastic and rubber technology process mechanics and are being managed by Harald Schnellenbach. The other two are being managed by Daniela Lombardi and are training to be industrial clerks.

We are delighted to have our new trainees and wish them all the best!

The full number of training trainees at BIW is actually 17.

From left to right: Ihsan Tokmak, Erdem Özdemir, Laura Schorz, Jan Hirschberg and trainee managers Daniela Lombardi and Harald Schnellenbach. Stefanie Pabst and Jan Steven Bolha are missing from the photo.

IMPRINT

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biw When it comes to competence