



Defining the Art of Silicone

MED: Helix Medical is known for silicone and thermoplastic medical components. What are the trends that you see coming?

Kley: Basically we see two big trends – one in silicone manufacturing and one in surface modification. In order to produce high-quality silicone products we exclusively use platinum catalyzed medical silicones. Talking about surface modifications there are several possibilities to adjust components to individual customer requirements. Friction reduction or antimicrobial coatings are gaining more and more importance.

MED: What are the advantages of platinum catalyzed silicones?

Kley: With platinum catalyzed silicone you don't need to worry about the emission of peroxide. During the manufacturing of platinum catalyzed silicone moldings and tubing there are no by-products contaminating equipment and finished goods.

MED: Does this help making production processes cleaner?

Kley: That's right. In fact it is state of the art, but some stay with peroxide silicones because they want to avoid the change procedures. We are exclusively using platinum catalyzed silicones for all our products from tubing to precision molded parts, from implants to other medical components. If peroxide silicone is used there always will be by-products remaining in the production and storage equipment. Helix Medical has never used peroxide silicones – so the cleanliness has been guaranteed from the beginning.

MED: Where do you use antimicrobial coatings?

Kley: One example is our voice prosthesis. One division of the Helix Medical Group called InHealth manufactures OEM products for patients after laryngeal resection. Those patients regain their ability to talk after a valve is implanted into their larynx. This valve must be changed regularly. Using an antimicrobial coating the emergence of a bio film can be held up and exchange intervals become longer.

MED: Can coatings wear off after a certain time?

Kley: Depending on the surface treatment process and the application surface coatings can wear off quickly or last for years. If a coating's only use is friction reduction during the assembly process the effect may wear off quickly. Other surface treat-

Antimicrobial materials, miniature multi-lumen tubing, catheters for neurovascular applications and individual surface modifications through plasma treatments – silicones and thermoplastics can be uniquely customized. Dr. Max Kley of Helix Medical Europe explains the art of customizing these materials.

ments that are meant to reduce friction on a longer term can stay for years. If you modify a part's surface itself instead of coating it the effect might last the component's life time.

MED: How important are coatings with active pharmaceutical ingredients?

Kley: At our Vistamed facilities in Ireland we are manufacturing products with active agent coatings. At the moment we are investigating the potential for additional applications and further developments.

MED: What makes the difference: raw materials or production processes?

Kley: In our markets we are limited to the raw materials that have the certifications for medical and pharmaceutical applications. Differentiation is possible by efficient and innovative processes and attractive value-added services, e.g. surface modifications, which help create tailor-made solutions. Nevertheless we are also working on innovative materials for medical applications. But the certification of new materials is a long process.



» Our tubes for hearing aids have a diameter of 0.2 mm. For silicone tubing this is almost as small as it can get. But we are still working on products with smaller diameter and wall thickness. «

Dr. Max Kley, President Helix Medical Europe

MED: Helix Medical offers a patented surface modification technique comparable to plasma treatments. What is the difference in comparison to common methods?

Kley: Both the process itself and the effect on the material are different from conventional plasma treatments. We created our technique especially for critical applications such as medical and pharmaceutical environments and achieved less interfering results than with common plasma methods.

MED: What are the benefits of these plasma etched molded parts?

Kley: We see an interesting potential for plasma etched molded parts – especially for silicone moldings with low shore hardness which have a tendency to sticking effects. The part's surface can be selectively modified by plasma etching which is beneficial for e.g. automated assembly lines. There will be fewer disruptions because of sticking silicone parts. This is very important for high-volume mass production applications. Also transportation can be made easier or parts can become oil or water repellent.

 **CONTACT**

Helix Medical Europe GmbH
D-67661 Kaiserslautern
Phone +49 (0)631 5341-7500
Fax +49 (0)631 5341-7600
www.helixmedical.de

MED: Besides materials miniaturization is an important topic in the med tech world. Do you see further development in this area?

Kley: Concerning miniaturization we see strong growth of demand for neurovascular applications for instance. There are numerous innovations which demand miniature components. Being development partner of innovative high-quality solutions this is an interesting field of development. Materials and production process set certain boundaries but we still see potential to push the bar. Today we manufacture implantable tubing with a diameter of only 0.2 mm. For silicone tubing this is almost as small as it can get. But we are still working on products with smaller diameter and wall thickness. A second impulse for innovation is the customers' demand for more functionality on smaller space. We offer multi-lumen tubing to the market which facilitates catheter systems with additional functions. The space these functions will be placed into becomes smaller and smaller. And again we work on pushing the bar even more.

MED: Where do you see more potential for new developments – at the material or the process side?

Kley: We see potential on both sides. But remarkable progress is most probable with a combination of both. The advantage of the Helix Medical Group is that we cover the entire value chain from research & development to manufacture and assembly of complete minimally invasive systems. For instance we offer development consulting and support by our subsidiaries Vista-med and MedVenture. By understanding the architecture of components and devices combined with our expertise in manufacture and material science we facilitate new func- »



» Remarkable progress will most probably be achieved by combining improved materials with optimized processes.«

Dr. Max Kley, President Helix Medical Europe

» tionalities. Being part of the Freudenberg Group we have access to the most powerful research & development entities which have been bringing innovations to the elastomeric and thermoplastic fields for over 80 years and offer the most modern analysis techniques.

MED: Are you working on a new miniaturized product?

Kley: Absolutely. Our subsidiary Cambus Medical in Ireland manufactures precision hypo tubes for sophisticated catheter systems. The colleagues are working on products with an extremely thin wall thickness yet high flexibility. The challenge is to develop the thinnest hypo tubes possible that won't break in its application.

MED: How long does such a development process take?

Kley: A complex project with different parties involved and approval procedures to be run through can easily take nine months up to several years.

MED: Do you use simulation models?

Kley: We have a simulation and testing facility with excellent equipment in Weinheim, Germany. There we can for instance simulate the influence of different design alternatives as a function of different material characteristics for our voice prosthesis using FEM. Tubing can also be an example. If the targeted properties are known we can simulate the tubing and find the ideal combination of materials.

MED: How important is Rapid Prototyping during a development process?

Kley: We have several development projects which we support

with rapid prototyping. Here again we have the big advantage of being part of the Freudenberg Group. In cooperation with our partner company Freudenberg Merkel we can offer prototypes and sealing components in small numbers within a matter of days.

MED: Is this the production process of the future or maybe something your customers could introduce to their own facilities?

Kley: For high-volume molded parts this stock-removing technique is not the method of choice. At our MedVenture division we use 3D printing technology during the development phase to manufacture entire catheter modules. In mass production materials and applications play an important role. Many materials which can be used for rapid prototyping are not applicable or do not show the necessary properties required by medical applications. Today rapid prototyping only allows a limited view on the final system. Certain functionalities can be tested but is an adequate product. In our markets 3D printing technology cannot yet replace traditional production methods in a bigger scale.

MED: You already mentioned companies you acquired during the past months and years. What is the intention behind that?

Kley: Today Helix Medical is one of the leading companies in manufacturing medical components. It is our aim to also become the preferred development partner and service provider for our customers developing complex medical devices. We will offer the complete value chain from material expertise to final assembly – but always in cooperation with a customer.

MED: Do you consider Asian suppliers as competition?

Kley: We see Asia as a big opportunity for us. The Asian market shows a growing demand for high-quality components and even complete devices. We are currently studying how we can expand our presence and activities in China. Regarding Asian components suppliers on the European and American markets we do not yet see an intensification of the yet high competitive pressure. As to liquid silicone molding the leading tool builders are all based in Western Europe and the United States. It is difficult to find equivalent support in East Asia. The infrastructure is not yet set up sufficiently.

MED: What will bring the Freudenberg Group forward in the medical markets in the next five years?

Kley: We have been growing considerably in a very demanding environment. The Freudenberg Group is soundly financed and possesses the necessary means to expand in the medical industry. The medical field is one of our target markets for sustainable growth. We will grow organically at all our sites. Furthermore we keep our eyes open when it comes to acquisitions.

MED: Where do you see your biggest market opportunities in the years to come?

Kley: We see considerable potential for growth in Europe. We have set up our European headquarters in Kaiserslautern, Germany in 2009/2010 only and have been intensively working

the European market since. Due to its strong market position Helix Medical still has solid potential to grow in the American market. Also Asia and Latin America are very interesting markets for us. In Costa Rica we have a production site in the leading outsourcing area of American medtec companies.

MED: Regulatory conditions play an important role in the medical world. How do you evaluate the draft of the new European directive?

Kley: As a component supplier we are following this development very attentively and with a certain anxiety. We see the threat of an overreaction. The key point will be whether the European regulatory system can preserve its advantage regarding reactivity and flexibility for innovations and developments.

MED: Could the European medical industry thwart itself?

Kley: Absolutely. But in addition to that it still has to be possible to bring innovations to market for the sake of the patient.

MED: Which are the positive aspects of the new directive?

Kley: I think a consistent execution of the existing legislation in the different countries of the European Union is a key factor. If the new directive will achieve that, it would be welcome.

MED: Thank you very much for the interview, Dr. Kley. ■

Company Profile



Colder Products Company

Colder Products Company is the leading provider of quick disconnect couplings and fittings for life sciences applications. Used in a broad range of devices and equipment, innovative standard and custom-engineered solutions for fluid and air handling allow flexible tubing to be quickly and safely connected and disconnected. Applications include reusable and disposable connection devices for use with surgical and dialysis equipment or on blood pressure monitoring and patient therapy devices.

Colder's engineered solutions improve the overall function and design of the equipment and processes in which they are used. These advanced coupling technologies improve OEM manufacturers' products with enhanced features for increased patient safety and reduced manufacturer liability.

IdentiQuik® Series couplings integrate radio frequency identification (RFID) to automatically identify fluid characteristics, track device usage or capture connection usage data before a connection is made, to prevent connection errors.



Hybrid Connectors allow fluid, air and electronics to be connected with one simple motion.

NS1 Series quick disconnect couplings are the smallest plastic non-spill quick disconnect coupling available on the market today. Available for tubing sizes less than 3.2 mm, the connectors provide a truly closed system and a cleaner, safer connection for small tubing diameters where space is at a premium.

Colder Products, a Dover company, has direct sales and distributor representation in North America, Europe, Latin America, Australia and Asia. Visit www.colder.com or email info@colder.com.

Colder Products Company

Germany

Colder Products Company GmbH
Schmalweg 50
55252 Mainz-Kastel
Phone: +49-6134-2878-0
Fax: +49-6134-287828

China

Colder Products Company Limited
Flat B, 29/F, West Gate Tower
7 Wing Hong Street,
Cheung Sha Wan
Kowloon, Hong Kong
Phone: +852-2987-5272
Fax: +852-2987-2509