POLYTECH

Health & Aesthetics

1986–2011

25 Years of Focus on Quality and Safety
A Quarter of a Century of Innovation and Momentum

In 1986, Ronald Reagan was President of the United States and Helmut Kohl Chancellor in Germany. Spain and Portugal became members of the European Union. In Dieburg, a company named POLYTECH was founded. It was also in 1986 that I started to work for the BVMed, and since I have witnessed POLYTECH’s commitment to our association’s activities.

25 years of POLYTECH stand for a quarter of a century of innovation and momentum – but this does not only apply to this company, it describes the medical devices sector as a whole. We are proud to work in a trade that provides assistance to people and in which we continually strive to improve patient care.

Medical devices are indispensable in health care and for a better quality of life. Medical technology is an investment in the life and performance of humans. Innovative medical technologies have to be available promptly to all patients in need of them. These core messages do not only apply to the sector of medical devices as a whole but in particular to Polytech and their special range of products.

It is my great pleasure to express my congratulations to POLYTECH and their employees for the 25-year anniversary and my best wishes for a continually dynamic and successful development!

Joachim M. Schmitt, BVMed

25 Years

Content

A Quarter of a Century of Innovation and Momentum
Joachim M. Schmitt.................................................................2

POLYTECH: a 25-year Success Story – Chance or Purpose?
An interview with founder Wilfried Hüser .............................3

Management Viewpoints
Patrick O’Leary, PhD | Pascal Hüser ..................................7

Because Implants Differ .....................................................8

Press Abstracts 2009 / 2010.................................................11

People at POLYTECH.......................................................12

Congratulations from ...
Prof. Christian Gabka, MD | Assoc. Prof. Klaus Exner, MD ....14
Klaus Brunnert, MD | Martin Kuerten, MD ............................15
POLYTECH: a 25-Year Success Story – Chance or Purpose?

An interview with founder Wilfried Hüser

Since the foundation of the company in 1986, Wilfried Hüser has been the driving force behind POLYTECH Health & Aesthetics. In team with his wife Beatrice, both decided 25 years ago to start their own business. They started as a supplier of medical devices for fracture treatment. Since then, POLYTECH Health & Aesthetics has become one of the market leaders for silicone implants in Europe and the only German manufacturer of soft-tissue implants, focusing on breast implants.

Today, the wide experience gained in a quarter of a century is combined with innovative ideas by the three directors Patrick O’Leary, PhD, Oliver Bögershausen, PhD, and Pascal Hüser. This leads to a continuous advancement in product development and services, supported by a lively dialog between POLYTECH, its partners as well as physicians and their patients. This exchange is a sine qua non and an integral part of the company philosophy which focuses on high quality and absolute safety of all marketed products.

POLYTECH developed a modular system of implants, an innovative and optimally systemized product line which helps physicians to choose the most favorable implant. At present, the product range consists of some 1500 implants and expanders, the focus being on breast implants for women. Additionally, pectoral implants for men, calf implants and gluteal implants as well as a large number of other soft-tissue implants complement the company’s portfolio.

Apart from this wide product range which had been produced in Brazil until 2008 and since has been manufactured exclusively in Germany, POLYTECH organizes meetings and workshops for interested physicians. At these events, experts catch up on state-of-the-art implant technology and discuss amongst each other optimum solutions on an interdisciplinary level.
On the occasion of the 25-year company anniversary Wilfried Hüser enjoys taking a look back at the different stages of the development of his enterprise. But being a visionary, he also likes to look into the future. In the following interview, the entrepreneur expresses his thoughts and insights regarding responsibility, sustainability, advancement as well as continuity and safety as elements of success.

What motivated you in 1986 to start your own business?

"Having worked as an employee in big international companies inspired me to become self-employed. The idea was themed ‘small is beautiful’ – and put into practice. At the beginning, we distributed medical devices for conservative fracture treatment. My wife managed all tasks in the fields of administration and shipping while I marketed and sold the products. Shortly after, we were able to hire our first employee."

For a certain period of time you had your products manufactured in Brazil. What were the reasons why you relocated the production to Germany?

"Still and rightfully so, German brands enjoy a good reputation worldwide and are synonymous for top quality and high-end craftsmanship. Especially in the application of medical devices, quality, and above all quality management, are of maximum importance. It
was our objective to create a situation where we are able to control our products intensively and apply advancements fast. These parameters can simply be provided for best in Germany."

- **In what way do the numerous cooperations contribute to the success of your company and the advancement in product development?**

  "In 1987, we started as a distributor of the Aesthetec/Natural-Y implants Même® and Replicon® with Microthane® coating. These implants were first described in 1970 by Franklin Lloyd Ashley. After the US-American manufacturers closed down their production due to the so-called silicone crisis, POLYTECH took over. Since 1991/92 we have manufactured these products under our own direction. We extended the product range with the Optimam® (anatomical long) and Opticon® (anatomical short) implants and perfected the polyurethane-coated implants. Active cooperation with numerous physicians permitted us to compile a wide portfolio of new products. To date, the cooperation based on partnership and the continuous dialog with physicians rank high for us and are pivotal for the successful adoption of our products."

- **What makes you different from your competitors? Do you have a secret formula for success for a company like POLYTECH?**

  We are different because we are driven by the desire to provide ever higher quality. And with us, it is not mandatory that this motivation loses priority against profit maximization. Today, this attitude is no longer widely called for. It does not matter whether we talk about the raw material, processing, documentation, packaging or sales, every single element of our production process is subject to the highest quality standards. Only this chain of regularly controlled conditions enables us to manufacture our products on our established quality level and advance their development. This, however, is something you would not be able to do without a motivated staff. I want to seize this occasion to express my heartfelt thanks to all the POLYTECH employees for their commitment. Without their dedication, our company would certainly not have become as successful as it is today. I am really proud of a team which combines competence and the capacity to teamwork in equal measure.
What visions do you have for your company if you look into the future? Is the present demand for implants only the transitory result of a short-lived trend or will it continue to rise?

We will strengthen our position in the market on a global scale focusing on South America and the Far East. To this purpose, we are recruiting reliable partners. Since our field of action is not limited to cosmetic augmentation but also has a stronghold in medically necessary reconstructions, I do not classify our company as a trendsetter. To the contrary – if we keep in mind that modern health care provides us with a kind of lifetime extension, reconstructive surgery will become ever more important in the future. For the years ahead, I expect a growing market and I will expand our activities also on a physical level. This year we will begin with the construction of a new production site, and I am looking forward to this expansion.

Wilfried Hüser, January 2011
Management Viewpoints

"POLYTECH Health & Aesthetics has been an exciting place to be for the past few years. We have changed our name, made the transition from having our products made by a third-party vendor to a full-fledged manufacturer and gone from selling mainly to Europe and former Soviet-block countries to a worldwide market place. In addition, we have developed a state-of-the-art product range in the Modular System, Sublime Line and Diagon/Gel 4Two line of implants, complete with their respective sizers and expanders. This is the largest offering of implants in the industry. Our team of researchers, engineers, regulatory and production people can bring to market products faster than any other company in the industry. This has been quite an accomplishment of which we are very proud.

But this is just the start! We have not only invested heavily in our product range and manufacturing facilities, but also in our distribution network. We have seen many new countries come online in the past year and are pleased to have relationships with new countries and POLYTECH starting on almost a monthly basis, for example in South America and the Far East.

The next few years should be even more exciting as we start to enjoy the fruits of our collective labor. This will be demonstrated in our ability to manufacture sufficient volume of excellent quality products that the market demands. Combined with our new distribution partners, we will take market share from our main competitors, the big players in the market.

I would like to thank everyone for their efforts in the past, present and future for helping to make POLYTECH a premier leader in the Plastic and Reconstructive Surgery field."

Patrick O’Leary (PhD),
Managing Director

"Through my parents I have, of course, been in the front row to follow the permanent advancement of POLYTECH since its foundation. I witnessed how a company operating on a worldwide level grew from a simple idea. Due to the company’s innovative products and their high quality, POLYTECH was able to establish itself as the only German manufacturer of soft-tissue implants focusing on breast implants.

Some twelve years ago, I started to work for POLYTECH as a sales representative. This happened during an exciting period, when plastic surgery and particularly the use of breast implants were booming. After eight years in the field, selling the company’s products in my area and at numerous international exhibitions, I took over the sales management for Germany, Switzerland, Austria and the Benelux countries.

It is mainly due to the commitment, the ambition and the joy which each and everyone of my fellow employees invests that we at POLYTECH Health & Aesthetics are looking forward to a bright future."

Pascal Hüser, Managing Director
Because Implants Differ

If people talk about implants, they primarily think of prostheses for the hip, knee, jaw or the female breast. But in this respect choices and possibilities are manifold.

Having a nose or chin implant, for example after an accident, helps patients to return to a "normal" life. For people with a congenital defect, for example in the area of the calves or the chest, an implant may strengthen their self-esteem and improve their quality of life.

Especially regarding the application of medical devices, quality and above all quality management are of utmost importance.

Quality „Made in Germany”

Taking a look at the production process at the POLYTECH Health & Aesthetics production site shows: every implant is a work of art and actually hand-made.

The first step is to manufacture the shells for the various silicone implants with the help of plastic moulds. In a second step, these shells are filled with silicone gel by hand; then they are vulcanized and afterwards controlled, also manually, for bubbles in the filling and defects or unevenness. Manufactured with great care, there are more than 1000 different mammary implants for reconstruction or aesthetic augmentation of the female breast.

Beyond that, the company produces a selection of prostheses for contouring the shapes of the male breast, the calves and buttocks.

Custom-Made Workmanship

Apart from the standardized implants, physicians regularly order custom-made prostheses made to measure for a particular patient. Such products are, for example, implants to compensate a funnel breast or buttock implants in individual shapes for patients whose affected gluteal tissue had to be partially removed. Even an auricle implant for reconstruction after an accident had once been manufactured by POLYTECH.
Whatever product concerned, the production is ruled by international quality standards. Part of this quality control is, for example, a tensile test where the implant shell is stretched to over 900 percent of its original size. In another test performed, they have to ride out a simulated car crash collision at 45 km/h. Only if all controls have been passed successfully, will the implants be released for sale.

**A New Generation of Breast Implants**

A larger and/or firmer breast is high on the wish list of many women. Breast augmentation with silicone implants remains one of the most popular cosmetic surgeries worldwide.

Women who want a natural breast shape and look are, however, sometimes afraid that the result of such a surgery will provide an artificial looking result. But this is not necessarily the case. A new generation of breast implants, manufactured exclusively in Germany, promises to give a natural look and feel as well as long-term form stability combined with a minimum of complication rates.

What is so special about the new implant type? The Diagon\ Gel® implants of the 4Two series are made to fit the female anatomy and their filling consists of two different silicone gels (see pictures on this page). The gel at the back of the implant is softer, the gel at the front is firmer. The firmer Shapar Gel at the front supports the breast tissue like a push-up bra, and this is why the aesthetic result of its implantation looks so natural and the shape of the breast as well as the position of the areola remain stable.
Breast Cancer: Breast Reconstruction with Silicone Implants? But of course!

After a successfully mastered breast cancer therapy many women are confronted with the question: breast reconstruction with silicone implants – yes or no? Often, the fear of complications, for example capsular contracture, implant rotation or dislocation, blocks the decision. The anxiety in view of these possible risks and repeated surgery, at least to exchange the implants, gets in the way. As a result, the women feel insecure and lose much of their quality of life.

But this does not have to be the case. Long-term studies show that these complications may be avoided to a large extent by choosing implants with a certain surface. Implants coated with POLYTECH’s special medical-grade polyurethane foam Microthane®, have a definitely lower risk of the complications as described above.

www.brustrekonstruktion.info: the German Information Portal and Online Guide for Breast Cancer Patients

For German-speaking patients, POLYTECH has set up a special-interest microsite to assist women in their decision for breast reconstruction: www.brustrekonstruktion.info. The guide provides information on the possibilities and methods of breast reconstruction, reports of women who had their breast reconstructed, posts by surgeons and general information on silicone implants plus a glossary of frequently used medical terms. The page is complemented by a list of links to specialized organizations and alerts on breast cancer and breast reconstruction issues.
"In Dieburg, Hesse, are located the headquarters of Germany’s only manufacturer of silicone implants. Wilfried Hüser focuses on reliability rather than price wars. (...) The POLYTECH catalog with its feel-perfect products is impressive. All in all, there are [around] 1,500 prostheses manufactured in serial production. (...) All implants are handmade in a clean room. (...) Joachim Graf von Finckenstein, a plastic surgeon from Starnberg [near Munich], praises primarily the fact that Hüser consults him regarding new products and sends his staff regularly to attend surgeries. (...) Over the years, POLYTECH has risen to become the third most important implant producer in Germany, right behind the industry giants Mentor and Allergan,‘ reckons Finckenstein, who also presides DGAePC, the German Society for Aesthetic Plastic Surgery."

"Implant manufacturer POLYTECH Health & Aesthetics easily outruns the economic crisis. As the company shared, the number of employees as well as turnover were kept stable due to its successful expansion in Europe."

"Worldwide, there are only twelve manufacturers of silicone implants. One of them is located in Dieburg, Germany: POLYTECH Health & Aesthetics GmbH. The company was founded in 1986 as a German-American joint-venture, but after silicone was banned in the USA in 1992, company founder Wilfried Hüser decided to continue on his own and relocated most of the production to Brazil. Last year then, POLYTECH closed down production in South America and relocated it completely to Dieburg, Germany. The primary motivation for us was that this way we would be able to control and develop our production more effectively,‘ states Wilfried Hüser vis-à-vis Medical Tribune."
People at POLYTECH

"Since January 1998 I have been working for POLYTECH. I was hired for the department of quality management, regulatory and clinical affairs whose management I took over in 2001. Work never gets boring for me since new challenges come up time and again and the corporate management always trusts my decisions. What drives me is to further improve the already high quality of our products and to harmonize this with the increasing demand for our products. I am particularly proud of our production team which grew tenfold over the years. They are deeply committed and realize any requests regarding quality, design and quantity."

Oliver Bögershausen (PhD),
Managing Director & Quality Management Director

"What intrigues me at POLYTECH is the unique combination of competent and committed employees. These people, combined with a flat hierarchy and a short decision-making process, are the driving force behind the company’s ability to develop and market new products on record time."

Aeilke Ham,
Product Development

"I have been working for POLYTECH for 20 years and I am really happy here. I enjoy the daily challenge of taking on part of the responsibility for the high quality standard of our products. I appreciate that in return my good performance is acknowledged adequately. And I am proud that we are the only German manufacturer of silicone breast implants and can produce under the best conditions."

Selahattin Acar,
Product Development

"At POLYTECH Health & Aesthetics I appreciate my interesting field of action which I manage autonomously, the job security, the regular working hours and my long-time team mates. People who are committed are rewarded with extended responsibility and will gain recognition by the corporate management. Despite the fact that many things have changed in the last years, the company has remained humane and the bosses accessible."

Juljana Proft,
Warehouse & Shipping Department Manager
Team Marketing

"People at POLYTECH welcomed me with open arms and only shortly after I had started I felt accepted. The company’s internationality and the field of plastic surgery were pivotal in my decision to apply for the job of product manager. To work with clients and partners of most diverse cultural and national backgrounds makes my working day exiting and broadens the horizon."

Sarah Leinfelder, Kirsten Glück

"To me, POLYTECH Health & Aesthetics merges the best qualities of the German small and medium sized businesses, who are the motor of the German economy: short decision-making processes, a high flexibility plus a compact administration. Due to the international orientation of the company and my daily work with our foreign distributors, my job remains enjoyable and captivating. This is also due to the fact that we attend to the complete range of marketing material, from the company website to product information and exhibition booths."

Kirsten Glück, Marketing / Media Design

Team Administration

"I started working for POLYTECH in 1993. When the company grew and began to operate on an international level, my field of action expanded from sales only to sales, purchasing and the support of our European distributors. Today, I am responsible for the organization of the sales backoffice and administration together with my co-workers Verena Knobloch-Dahms, Claudia Weber and Jesko von Scheliha."

Maria Bichler, Manager

"I appreciate working in a team and enjoy the daily contact with ‘my’ clients as well as the diversity of my tasks and the prompt flow of information in our open-plan office. Also fascinating is our close cooperation with the production department."

Claudia Weber, Administrator

"It is the hot line to our clients which makes my day. I simply love being in contact with different types of people and at each call I am curious as to who is calling and what his request will be."

Verena Knobloch-Dahms, Administrator

"Our worldwide contacts make my job very exciting. Constantly, new countries with new clients join us. It is fascinating to watch how relations develop from the first contact to a successful partnership in the different markets."

Jesko von Scheliha, Administrator
Congratulations from ...

Professor Christian J. Gabka, MD

“For more than 20 years I have appreciated working with POLYTECH as I am convinced of their high implant quality. I particularly value their large range of different implant types which provide anatomically well-dimensioned proportions combined with natural haptics.

The professional contact with the company’s employees is excellent. The continuous and intensive dialog between the product developers and myself enables me to communicate my experience and my patients’ feedback to the manufacturer. This way, I can actively participate in the advancement of the products.

Apart from my clinical experience, the dialog with the manufacturer gives me the certainty that I am offering up-to-date top-quality silicone-gel implants.”

Associate Professor Klaus Exner, MD

“The high quality of POLYTECH implants is something I have been appreciating for more than 20 years. I really enjoy working with this company. We are cooperating scientifically and clinically in a permanent exchange mode. I continually share my experience with the company as well my patients reports. This way, I can actively participate in the advancement of the products, for example regarding quality aspects, shapes, surface design and mechanical properties of the implants. With this state-of-the-art implant technology I am always able to offer my patients an individual, optimum and safe solution.”

Christian J. Gabka was appointed professor in 2004 by the Ludwig Maximilian University in Munich. Apart from managing a private clinic, he is Head Surgeon of the Plastic Surgery Department at the Hospital of the Ill. Order in Munich Nymphenburg.

Associate Professor Klaus Exner teaches at the Johann Wolfgang Goethe University in Frankfurt and is Head Surgeon of the Clinic for Plastic and Aesthetic Surgery, Reconstructive and Hand Surgery at the Markus Hospital in Frankfurt. The clinic is internationally renowned as a center for aesthetic and reconstructive breast surgery.
Klaus Brunnert, MD

"My long-time cooperation with POLYTECH is based on reciprocal trust and a continuous dialog. I particularly appreciate the constantly high quality and permanent advancement of the products regarding their compatibility and safety. This is why, for more than 20 years now, I have been using mainly POLYTECH’s Microthane®-coated implants for breast reconstruction. With them I avoid re-operations, especially with former cancer patients. My experience shows that with this implant type the complication rate is definitely and considerably lower than with implants providing other surfaces."

Klaus Brunnert (MD),
Osnabrück

Klaus Brunnert, MD, is specialized on the oncological, surgical, adjuvant and palliative therapy of the breast carcinoma as well as on plastic, reconstructive and aesthetic breast surgery. He is Head Surgeon at the Clinic of Senology (breast surgery) in Osnabrück.

Martin Kuerten, MD

"What I appreciate most in cooperating with POLYTECH is the high quality of the implants and the wide range of training and information services they offer to plastic surgeons. Moreover, the company continually advances the development of their products and shakes up the market with their groundbreaking novelties. There are, for example, the Diagon\Gel® implants of the 4Two series, whose filling consists of two different silicone gels. The great thing about them is that I can pass on their benefits directly to my patients and offer them – apart from the natural aesthetics – additional medical advantages. Due to the particular form and consistency, certain risks can be reduced when using this implant type. This is why complications like implant dislocation or rotation occur significantly less than with other implant types."

Martin Kuerten (MD),
Mayence

Martin Kuerten, MD, is a specialist for aesthetic surgery of the breast and nose as well as for lifting interventions. Since 2008, he complements the team of aesthetic surgeons at the Fort Malakoff Clinic Mayence.