

OHST turns 80

30 years medical devices made in Rathenow



Content

Page 2

Steering a course through the uncertain Nineties

Page 8

A family company in transition

Page 14

Would you like to know how we work?

Page 28

Quality assurance is a question of responsibility

Page 34

OHST for Rathenow

Page 36

Engineers, surgeons and Zen Buddhism

Page 40

A personal contact for every requirement

Page 44

80 years OHST 30 years of medical products



Stephan Dunke, Board Member for Markets

How time passes! I can vividly remember the fortieth birthday of our father Norbert Ohst. That was in 1991, shortly after German reunification. At the time our grandfather Wolfgang still came to the office every day. It was due to him that the company remained in family hands during the GDR period. However, these were very different times and old-established customer relationships no longer existed. Our father had to look for new targets for the company, and then define a strategy for achieving them. He decided to focus consistently on the field of medical products. Even in those days this was not an easy option, but seen from today's perspective it created the basis for the successful development of our company. Today, 25 years later, we have completed the next generational change. Our father has retired and

for the family firm. Nowadays, too, we are once more faced with major challenges. Combined with a new medical device directive and increasing competitive pressure, the ongoing internationalisation of the industry is creating a highly dynamic market environment, to which the company constantly has to be adapted. We look forward to facing these challenges, because we have confidence in the team we have built up within the company, who have the motivation and foresight to master the tasks that lie ahead of us. As a quality supplier on the market we have a great responsibility to our customers and to patients, as well as an obligation towards the founders of our company and its 80-year tradition. We hope you will enjoy reading the following pages, which show our company from different perspectives as well as the enthusiasm with which all those involved approach their work.

Stephan Dunke

Steering a course through the uncertain Nineties

Norbert Ohst – a portrait

30 years have passed since OHST Medizintechnik in Rathenow produced its first acetabular cup. Today the name of OHST is a synonym for the production of high-quality joint implants. The rapid development of the company was driven forward by Norbert Ohst, who was born in 1951 and has now recently retired.

He's a dedicated sailor, and a picture by the dining table in his flat near Berlin's Wannsee shows him participating in a yachting competition on the water. Visitors are enthusiastically greeted by Streumer the dog, and receive the down-to-earth instructions: "Don't worry about taking your shoes off." The conversation is regularly interrupted by the dog, providing its owner with the chance to reflect – an opportunity which appears to be just as welcome as the occasional cigarette.

In the uncertain Nineties Norbert Ohst kept the Brandenburg company on a steady course. He spontaneously took a number of decisions which have influenced OHST Medizintechnik to the present day, and have enabled the development of outstanding products. During the upheaval in eastern Germany – a period during which most companies in Brandenburg went under – Norbert Ohst developed his father's company in Rathenow into a modern industrial enterprise. He invested in plant and machinery, established a section for sterile packaging

and set up an R&D department which today is manned by 10 engineers. In spite of this Norbert Ohst remains a modest person. Although his actions demonstrate determination, stamina and speedy reactions, he himself modestly talks of "opportunities which simply came his way".

The optical industry developed in Rathenow two centuries ago. When OHST was founded in 1937, there were still more than 200 companies supplying the oprical industry. "Every backyard had an optical or spectacle workshop, and my grandfather built the tools for them. My father was only 19 when he took over the tool-making



Norbert Ohst, chairman of the supervisory board

company. He later developed, constructed and exported paper testing equipment."

Just like his father Wolfgang, Norbert Ohst himself also became a toolmaker. "I worked in a state-owned company as a toolmaker, was then sent off to study and became department head at ROW, the Rathenower Optische Werke." In 1985 Norbert Ohst joined the family firm, in which six technicians mainly made paper testing machines. In the Sixties, when most GDR companies were taken over by the state and became production cooperatives, Wolfgang Ohst remained independent: "In the

GDR our paper testing machines represented a successful export, which meant that my father was generating foreign exchange. However, he was not permitted to expand until the end of the GDR regime. Because my father was not in good health, in the mid-Eighties I took over the management of the company and, converted the way the paper testing machines were produced. Finally we added a further production division in the form of medical technology."

4 | Steering a course through the uncertain Nineties | 5

Future-Workshop over a couple of beers

When the Rathenow toolmakers were invited to a reception at the GDR's Academy of Sciences, they by chance met doctors from Berlin's Charité hospital. "In 1985 there was a get-together for the metalworking industry in Berlin, and in the course of a conversation with professors in the bar we were asked if we would be able to make acetabular cups from polyethylene. What testing equipment for the paper industry and acetabular cups have in common is that they both contain components which are produced and fitted in precision engineering. This fortunate circumstance was our entry into medical technology, with production of around 1000 acetabular cups per month since 1986.

In the uncertain Nineties
Norbert Ohst kept the
Brandenburg company on
a steady course

The biggest problem was getting the material, because at that time it was only produced by one company worldwide, and of course this company was located in the non-socialist economic zone. The manufature of the first prototypes was quite an extraordinary story. At the Charité, the GDR's model hospital, one of the professors was to operate on a female patient from West Berlin. She crossed the border with a piece of Chirulen polymer and used it as payment. Together with the doctors we made drawings and then used this piece of Chirulen to produce around 500 acetabular cups, which were then clinically tested." The synthetic material which had been smuggled into East Berlin by the patient was the starting point for the mass production of acetabular cups for a number of socialist states. The GDR's Department of Foreign Trade then assumed responsibility for procuring the Chirulen.

After German reunification it was possible to obtain the raw material on the open market, but the OHST production of acetabular cups initially seem to be doomed: "GDR production built up stocks, but competition was now coming from established companies in western Germany



Mueller II Cup made of Chirulen (UHMWPE) (page 4) Production facility in the forties (image, left) Clean room at Falkenweg in Rathenow,

Clean room at Falkenweg in Rathenow, former production facility (image, top right) First CNC-machine at Falkenweg (image, bottom right)







and Switzerland." Ohst modernised his paper testing machines: "We invested a lot of money and the feedback from customers at trade fairs was enthusiastic, but at the same time the paper industry was in a recession." We were told: "We love your machines, but we aren't in a position to buy them". We then spent a lot of money buying a structurally complete factory shell from the 'Treuhand' financial reconstruction organisation, and my staff painted the old machines from 1935 and 1940 green, so that they would look modern." OHST received supply contracts for ROW and bought its first CNC machine. "Everything went fine for a year, but unfortunately we weren't paid - the customer went bankrupt." Ohst almost met the same fate, because with the Rathenower Optische Werke he lost his biggest customer.

In a change of tack Ohst then called on his experience in the production of endoprosthetics. "We located a company which wanted to obtain

complete artificial hips, in other words the hip stem and acetabular cup plus head. In 1994 the first designer was employed, we also needed new personnel for the CNC milling machine, and then we continued to grow, around 20 to 30% every year. Focusing on medical technology was the best decision I ever took." Ohst steadily expanded his product range, adding knee joints and surgical instruments to the hip components. Thanks to his own R&D section he was able to extend his product spectrum at a rapid rate. He travelled the length and breadth of the country in

6 | Steering a course through the uncertain Nineties | 7

order to obtain new production orders, publicise his company and visit the competition: "I said to them: we want to make the same products as you. Can I produce the sort of stuff for you which you don't feel like making yourselves?"

We need to roll up our sleeves

"In 1995 a sales representative from the West came to me and said he had a great customer in the USA, with whom we could make sales of 5 million in the first year. We produced and delivered goods worth a million dollars to the USA, and my partner travelled over there, put the million in his pocket and was never seen again. We had completely financed the order in advance – I wasn't naive, but I thought that I knew him. When I told the bank that he had disappeared, they closed my storage facility and blocked everything. The million was due immediately and I didn't have the money, because at the end of the month I paid out everything that I could scrape together."

Ohst didn't give up. "I said to my people: We need to roll up our sleeves. I don't know if I can keep the company going, but if we manage it and I start earning money again, you'll get your share. Are you with me or not? And they all stuck with me." After three years he was able to pay back what he owed the bank, and his workers received a pay rise. "And from 1998 things with the company began to improve." The mutual trust and the close personal ties between Ohst and his workforce had been developed over the years. Personal contact took pride of place within the originally small family company: "So until 1995 I walked round every day and talked to everybody." Ohst





Setting-up of an early CNC-machine (image, left) Operating a conventional milling machine (image, middle) Check of usability of an instrument (image, right)

recalls: "I experienced that most recently during the floods in Havelland in the spring of 2002. I asked my guys if they were prepared to shovel sand and fill sandbags on the Saturday and Sunday. They were all there. They worked as if they were fighting for their jobs.

A handshake counts

The dog Streumer brings a stick from the garden, gives the visitor a friendly greeting and chases a small rubber mouse. "Down boy!" calls Ohst. "Until 2002 the approach to business was very different – it was all about dealing with your customers in person. It wasn't all based on a handshake, like in the GDR, but everything was agreed by mutual discussion first, and then finalised on paper later." Norbert Ohst has a lot of time for people who have real enthusiasm for something.

"This is how our support for the FSV Optik football club developed. We are the main sponsors – without us they wouldn't be able to play at this level. I got to know the coach and the players – they're friendly and cooperative and don't drink any alcohol, they're real athletes." The sailor clearly finds his own values reflected here.

The construction of today's production facility in the Rathenow business park of Grünauer Fenn also represented planning with foresight, but nobody was able to know in advance whether the investment of €7 million would pay off.

OHST Medizintechnik has been able to expand its position on the market on the basis of this location. "We expanded the facility in 2005.

Whenever we invited customers to the building for the first time they were generally very impressed and often placed the order we hoped for." Ohst introduced a quality management system at an

early stage. "In this area we took the lead in the field of medical technology – it was foreseeable that this would be required one day."

Today the increased demands on manufacturers of medical products and the internationalisation of the industry after 30 years have led to a new change of generations at OHST. Norbert Ohst's sons have taken over the management of the company: Stephan Dunke has been with the company since 1997, and has been Board Member for Markets since 2003. His brother Sebastian Sturm, who is now Board Member for Markets, joined in 2008. "Our quantities and batch sizes have changed, which requires increased flexibility. Our machinery is set up for this and we are outstandingly equipped in technical terms, but acquiring customers takes significantly longer nowadays. However,

He says that from the very beginning controlled quality and care have been important to him

the future of the company is secure." Ohst's confidence is based on sustained development work and confidence in his own workforce. He says that from the very beginning controlled quality and care have been important to him, because he was very much aware of the fact that his products are integrated into the human body. The word 'learning' is something you hear again and again from Ohst: "We learned from every contract, and my work as a manager was a constant process of development for me."



Norbert Ohst and his sons Stephan Dunke and

A change of generation and new management models at OHST

Norbert Ohst has retired, and today his sons are in joint charge of the company. Stephan Dunke (Board Member for Markets) has been with the company since completing his business management studies 20 years ago, while his brother Sebastian Sturm (Board Member for Production) joined nine years ago.

How do you divide up your tasks?

STEPHAN DUNKE

It's an advantage that there is little overlap in our areas of responsibility. We have the possibility of mutually inspiring each other. I started by dealing with commercial operations, then took additional charge of R&D, and now as Board Member for Markets I'm also responsible for customer matters.

SEBASTIAN STURM

I'm a lateral entrant to the business because after completing my state examinations I first worked as a lawyer in Berlin. I then decided to join the company full-time and initially worked in purchasing before I took on the job of Board Member for Markets.

STEPHAN DUNKE

We were able to get used to our responsibilities over a long period of time.

SEBASTIAN STURM

Our father withdrew from the company step by step. He no longer wanted to take all the decisions himself and expected us to fill the gap.

How does the family function within the company, and the company within the family?

STEPHAN DUNKE

This also has two contradictory sides. I have an obligation to my work and at the same time a responsibility towards my family. As a member of a business family you can't simply make a clean break and start afresh somewhere else. You have to grit your teeth and solve whatever problems come up.

SEBASTIAN STURM

It is continuity which distinguishes us as a business family. We correct any faulty developments, even if it takes months or years. Sometimes this also means insisting that in the future something should be done differently from the way it has been implemented over the last 15 years.

STEPHAN DUNKE

The long-term continued growth of the company is our shared target. Whatever action we define has to serve this purpose. Whenever there is a difference of opinion it is this objective which is the deciding factor.

Do you talk about the company in your free time?

SEBASTIAN STURM

When we get together, whether it's at the sailing club or at home, we always end up talking about company business, too.





It's always useful to be able to talk about things at a certain amount of distance. Our father looks at the matter in the same way.

Stephan Dunke, Sebastian Sturm and Norbert Ohst

So your father is still playing a role as an advisor. Are you measured by his standards?

STEPHAN DUNKE

When a new chief takes over people always say: things were much better in the old days. For us the important thing is to develop the company further, and when it comes to taking important decisions our father is always there to provide advice if necessary.

What are your personal strengths?

STEPHAN DUNKE

Thanks to my contacts with the market I can stay up-to-date with trends in product development and the latest requirements in the regulatory field. This means that the strategic further development of our products, in which I work closely with our our R&D department, falls under my responsibility. In the case of Sebastian it's the operational business of production, which is much more detailed. In my opinion the strengths we share are the ability to break down complex issues and provide our personnel with targeted support in their work.

What is the special feature of OHST Medizintechnik from your point of view?

STEPHAN DUNKE

We develop and produce medical products, and use the applicable technical documentation to prove that they are suitable for implanting and use in the human body, and in addition are supplied in sterile packaging. We offer the entire value-added chain for both implants and instruments, from development via the approvals process to series production. This is a rarity in the field of contract manufacturing. In the area of surgical instruments, a few years ago together with an industrial designer we established a standard which enables us to create a certain 'wow' effect based on the trays, surface finish and handles which we use.

SEBASTIAN STURM

Users need to feel comfortable with the instruments, they should actually look forward to working with them.

How is this wide product and service range reflected in your corporate structure?

STEPHAN DUNKE

The integration of an R&D department was an important step. In 1994 we were still showing products to Heiner Genrich, our first designer, for him to copy. Today it's the other way around and our customers see us as the ones providing the experience. The integration of sterile packing operations was equally important. Both are highly critical processes.

SEBASTIAN STURM

Regulatory requirements are becoming more and more extensive. They apply to selecting the materials, the operating resources used in production, and cleanliness in the workplace. In the CNC processing of synthetic components we avoid the use of cooling lubricants, for example, so that we don't have to remove them again later.

STEPHAN DUNKE

In 1990 implants were still delivered to hospitals in a non-sterile condition. Nowadays the manufacturer is responsible for the final cleaning and sterilisation. Our implants go straight into the operating theatre. There are no intermediate checks or cleaning processes. Our distributors supply the hospitals directly. They audit our process descriptions and documentation. Our advantage is that during the period after German reunification – when we were in the process of concentrating on medical products – we had the opportunity to set up a quality management system at the same time. We received certification in 1995, which means that we were one of the first in our industry. Everything which is now added is only a further piece of the puzzle.





Stephan Dunke, Boaerd Member for Markets

How do you develop new products?

STEPHAN DUNKE

Our users in the hospitals need partners in order to transform their ideas into medical products. This is our opportunity to move into new product segments. In the past we concentrated mainly on hip and knee joints, but currently we also have an ankle joint under development. These projects, for which we bear the development risk, will in future enable us to set ourselves off from other contract manufacturers.

Five years ago only around 3% at most of your production was exported. The export proportion of your production has now risen to about one third.

STEPHAN DUNKE

We had the good fortune to grow together with our customers, and have been able to ensure that this growth is sustainable. Today there is pressure on the industry with falling prices and declining quantities on some markets, while the requirements of the market, too, are changing. We have to open up other markets - in recent years we have been able to constantly build up the proportion of our goods which is exported, and for the future, too, we see tremendous potential in our international business.

Do you still take management decisions based on a gut feeling?

STEPHAN DUNKE

Our customers, too, have changed. Today our operations are highly bureaucratic, with quality management getting involved and checking that we're doing everything the right way. There are lots of requirements and a large number of individuals who work together with us and have an influence on the decision-making process. For me personal communication is very important, and this close communication is also a central factor within our sales team, who act as contact persons to the individual customers.

SEBASTIAN STURM

Today we define with great precision why we need a new machine and exactly what it will do. For the purpose of validation studies we have to determine how many cycles we operate. Changes are significantly more difficult to implement, but it also means that the likelihood of a false investment is reduced. Our authorisation rules in procurement are also an example of this, because structured purchasing processes and economies of scale offer significant savings potential.

STEPHAN DUNKE

In the same way we also check the liquidity and the potential of every new customer, instead of taking a decision on the spur of the moment. Initially this slows things down, but in the long term it leads to continuity and consistency in the evaluation of business processes.

How has the communication within your company changed?

STEPHAN DUNKE

Nowadays we look in much greater detail at the operating areas of individual employees. This puts us in a position to communicate any new topics to all our personnel within 24-hours, and make sure that all information is passed on. We retain the relevant know-how within the company by documenting all processes. Within the context of our quality management we create procedural descriptions for all critical processes and for procedures which are timeconsuming and regularly repeated.

SEBASTIAN STURM

In spite of this new employees of course need a certain amount of time until they have acquired the right touch for specific activities, and in a number of areas our young staff can be much more skilful than some of the old hands.





a lighted magnifying glass

OHST endoprosthetics production in Rathenow

There's no doubt that companies based on the outskirts of a big city are more accessible than companies in rural areas like the Havelland region. However, there are few manufacturers in the endoprosthetics field which can offer such a wide spectrum of products and services as OHST. The family firm has been based in Rathenow for 80 years now. Accessible from Berlin in only 50 minutes by train and closely networked with health research in Germany's capital, OHST has been making medical products for 30 years now and today offers a full

product spectrum of endoprosthetics and surgical instruments. The family company may over the years have developed into a modern industrial concern, but the OHST principle continues to apply: localised production enables the achievement and checking of high quality standards, and this is why the development, production and sterile packing of prosthetics and operating instruments are all implemented in Rathenow. A workforce of 140 well-qualified technicians enjoy optimum working conditions here and apply the latest technology.

Station 1: Production scheduling

In the incoming goods area of the OHST company building, which was constructed on the Grünauer Fenn business park in 2001, we meet Florenz Engel, partly concealed behind a trolley full of pallets with metal blanks in all sorts of shapes. He is in charge of production scheduling: "When somebody orders a prosthesis we make sure that it is available exactly at the time when the customer needs it", he explains obligingly. "For this purpose I have to make production capacity available and if necessary purchase the relevant materials." However, production is not always related to a specific order. OHST has a modern storage system. "At present we have just under 10,000 articles in our sales programme, and they are all listed at the minimum inventory level."

80% of what OHST produces consists of OEM products, which are sold under the company's own name. The other 20% consists of contract manufacturing to customer specifications. The OEM standard products are directly available and can be ordered at short notice, with



Florenz Engel, Head of Supply Chain Management

In the south of Berlin, where I have lived for 25 years, I previously worked for 23 years at a company which had developed from a midsized family company into a large corporation in the field of environmental technology. For me work at OHST is an interesting challenge, because the company has grown fast and a lot of processes can be optimised. I experience a lot of appreciation here, and because of my experience I'm often asked for advice. And of course it's great to make a product which helps people. My work here leads to discussions with friends and acquaintances about people who have already taken advantage of this service. A friend of mine could hardly move because of the pain in his hip, and today enjoys complete freedom of movement. It's always exciting to see how products are developed, how many different considerations go into them, and how high the statutory requirements on them are.

follow-up production triggered as soon as existing stocks fall below a certain level: "OEM products are delivered as soon as the customer places an order. In contract manufacturing goods are produced within a specific period specifically for an individual customer." The close interlinking of the sales, procurement and production scheduling departments means that OHST achieves both short delivery times and complex manufacturing processes. Engel and his team of three schedulers plan every operating stage in the production process two weeks in advance.

Transparent and controlled enterprise resource planning (ERP) is standard practice in modern industrial companies. It makes it possible to calculate any special features of the company's operations in advance and enables adjustment for any time delays. Engel regards himself as a mediator between sales and production. "We are responsible for carrying customer expectations over into production. The material and the capacities have to be available at the right point in time. It's a task for scheduling operations to balance customer enquiries and our production capacity." The articles which make up the



cast blanks in the incomming goods inspection

incoming goods at OHST range from raw materials to complex components from suppliers. The procurement section orders any materials which are not available on site in line with requirements. Suppliers of raw materials and service providers are selected carefully, and any divergences from specification are quickly identified by immediate checks. The incoming goods staff check that the right goods have been supplied in the right quantities, and pass them on to the next testing point for an evaluation of the quality. As a result it quickly becomes clear if materials do not meet requirements.

The integration of a sophisticated scheduling system within the everyday operations of the family company is supported by the communication structures at OHST, which range from daily meetings involving staff in different departments to a weekly conference among the heads of department. It is the result of a workintensive process of transformation.



Control panel of a 5-axis milling machine

Station 2: CNC production

For a moment we are standing alone in the OHST factory, surrounded by a large number of computer-controlled machines. At OHST production covers all work processes for the manufacture of implant components and surgical instruments: computer-assisted metal processing and manual grinding and polishing, as well as a range of testing methods. Fred Herrmann is in charge of CNC production in the area of 4-axis milling. What do you do with such machines? "We mill either part connections or complete

components from the raw materials." What's the difference between milling and turning? "In milling it's the tool which moves and the raw material is clamped into position, but with turning it's the material that moves and the tool remains fixed in position." Only computer-controlled milling machines are used at OHST. A number of machines are retooled automatically. Herrmann rotates a tower containing a number of implant blanks into the processing zone of the machine: "We mill a connection into these blanks. When

the workpiece comes out of the machine I check the measurements", explains the cutting machine technician, because in spite of computercontrolled operation the workpieces don't always comply with specifications: "Tool wear and tear is a significant factor. Of course we know from experience when individual tools have to be replaced, and we have to keep an eye on this. In working on the machine it's a matter of very precise settings, and we exchange experiences in this respect." For Herrmann teamwork is decisive when it comes to quality, especially with regard to the diversity of products which are manufactured. "Most of our 2,000 or so articles in the area of the 4-axis milling machines here are produced in small series, with an average batch size of 25 per order. In our two-shift system there is a handover procedure, with the second shift arriving a quarter of an hour earlier in order to find out from the early shift what parts still have to be processed. As a rule the first team completes any eight-hour job and and sets up the machine for the next operating process." This is the only way that the necessary documentation of operating processes can be implemented in line with quality management requirements. Quality control is a special feature at OHST. "I've now been at OHST for eight years, and before that I specialised in assembly work. When you're young you can do more or less any job, but when you get older the right working conditions become more important."



Station 3: Sales

Change of scene to a Wilhelminian villa in the centre of Rathenow: this is home to the R&D and Regulatory Affairs division, as well as the OHST staff who deal with customers and potential customers. Kristin Winterfeld is the Head of Sales at OHST, and deals with a wide range of customer enquiries: "From time to time we receive calls from patients who have seen our label on their prosthesis pass, and wish to ask questions about their implant."

Strategic selling

With qualifications in technology and product development, business administration, economics and marketing, the sales team surrounding Ms Winterfeld covers both commercial and technical know-how, which puts them in the ideal position to advise customers. In spite of this, the department is relatively small. "With a team of four we provide support for the whole world", jokes Kristin Winterfeld. As a manufacturer OHST concentrates on developing and producing endoprostheses. When she started at OHST in 2005, initially

in order processing, offers were still drawn up by management. The sales and marketing operations for communication with customers has been set up over the past decade. At present the Board Member for Markets provides support in particular in direct appointments with customers.

The targeted production of endoprostheses in accordance with customer requirements and for external sales requires close coordination among various departments. Before a production order is implemented, the Key Account Managers look at the drawings provided by the customer and draw up checklists relating to the quality and improvement potential of the components. With the production technology department they then plan the production process in detail. The customer then normally receives a production process plan within two or three working days, showing the sequence and the machines involved in the manufacture of the product. Expectations relating to market price and customer requirements are involved in calculating the production costs. When customers compare

the prices of offers which are not equivalent, this can lead to difficulties: "In this case the Key Account Manager has to explain the quality features behind our price, together with the factors which distinguish our products and services from competing offers."

As a manufacturer offering premium quality, OHST applies demanding criteria to the product quality of each individual part. After an order has been placed, the sales section tracks the status of the project all the way from the initial scheduling to the completion of production. The corrective and preventive action (CAPA) system integrated in the company's organisation includes on the one hand experience from the production of previous products, and on the other identifies possible deviations from specification well in advance. If necessary the customer is consulted before the next stage of production: "We inform customers about any aspect which could interest them, so that they can decide for themselves what their product should look like". This ensures that products meet their requirements. In spite of this, it can occasionally happen that customers



22 | Would you like to know how we work? | 23

modify their original drawing because the calculation of a specific tolerance turns out to have been too tight. In such cases the customer support team acts as an interface with the production technology.

The sales team also plans the production of OEM products: "We discuss requirements with the customer and then adapt our internal advance

planning with the scheduling section, so that we don't have any supply problems later." The work of the sales team also involves discussions with regular customers relating to "the use of implants and reaching agreement on their functions.

On the basis of our monitoring of the market we pass on to the R&D section any concrete criticism of our products or suggestions for improvements."







Gerd Hielscher and Stephan Dunke in a conversation with potential customers at MEDICA (image, page 22)

Marcus Liebert discussing with a customer (image, left)

Gerd Hielscher and Diana Delvalle Silva in a conversation with a potential customer (image, top right)

Visitor at the OHST booth (image, bottom right)



Meeting customers

In recent years the OHST Sales Team has represented the company and its products at a number of domestic and international trade fairs. OHST regularly sets up its stand at MEDICA in Düsseldorf, the world's premier medical technology trade show. Here the focus is on maintaining customer relations and the presentation of new OEM products: the sales team invites customers to MEDICA in order to inform them about new products or further developments in endoprosthetics and instruments in the company's product portfolio, and to maintain personal contacts. In customer discussions interested parties can obtain information about the products made in Rathenow and experience their quality

at first hand on the basis of the exhibits on display. At MEDICA, says Ms Winterfeld, the OHST sales team also welcomes international customers "who can't simply pop in and visit us in Rathenow". In addition the customer support team and product managers attend trade fairs and congresses both in Germany and throughout Europe, discovering innovations and monitoring the market for new trends in endoprosthetics and instruments.



Siegfried Meier, in charge of training and the apprenticeship workshop

Rathenow is my home. Initially I worked at ROW, as a master craftsman from the end of the Seventies, and then later at the firm of Duncker. I've been with OHST since the mid-Nineties. Here there has been constant investment, which is highly motivating because you notice that the management is continuously driving the company forward. In medical technology it is the materials in particular which are special. People nowadays are living longer, and it is therefore important for them to be able to enjoy their old age free from pain. The landscape around Rathenow is very attractive, but companies here will only be able to develop if we can keep our young people from leaving. I always say that they can't all be allowed to leave. When they do an apprenticeship with us young people learn all about the possibilities of modern technology, and they can then work anywhere later. I regard it as my task to ensure that the apprenticeship process benefits our company and region.

Josephine Blümbach, Apprentice in her third year

When I was at school the teachers told me I was good at working with my hands, and I decided to make a career of this. When I tell them that I'm training to be a cutting machine technician the boys are normally unable to hide their surprise. But being a cutting machine technician isn't necessarily a male occupation and doesn't involve heavy physical work - and it's a job in which there is always something new to learn. I don't find any stress in working together with men. It's amazing what can be produced with these machines here. I wanted to make something which helps people, and there will always be patients who need new joints. My grandma has had a hip replacement operation, and I think it's great that this really proved helpful to her. I like the working atmosphere here at OHST: the machines are state-of-the-art, it isn't a huge anonymous company in which people don't even say hello to each other, and it's in Rathenow - all my friends and family are here, it's home.



Station 4: Training at OHST

Family companies are renowned for stable, long-term development, with local roots which make them an important provider of jobs and apprenticeships, especially in rural regions. Young specialists find good working conditions here as well as the team spirit, the opportunity to work on their own initiative, and flat hierarchies. At the OHST training workshop in Grünauer Fenn we meet Siegfried Meier, who is in charge of training and thinks these factors are decisive in terms of the future capabilities of a company: "We train people here so that we will have qualified personnel later. Our apprentices wish to work here and manufacture products

from which people will later benefit." Anyone who has completed an apprenticeship as a cutting machine technician at OHST knows the operating processes at the company, the specific properties of metals and plastic materials in the medical field, and the technology applied. "Our apprentices are trained to work with our products and materials, and therefore have fewer adaptation problems than employees who come from a different industry." As a family company based in Rathenow, training young people from the region is vital for the existence of OHST: "We offer young people attractive jobs and the opportunity to develop their careers

here. We have modern technology and with a product spectrum of more than 10,000 articles our production is highly diverse, which presents ever new and interesting challenges." Those who do an apprenticeship at OHST can stay in their home region and get involved in programming or product development, for example. Over recent years OHST has greatly expanded its training operations: "We started with one apprentice industrial mechanic but today we often have eight apprentices, with the main focus on training as cutting machine technicians." This training programme counteracts the "natural wastage" which arises when employees leave the company

or retire. In the training workshop we meet
Josephine Blümbach, who is training at OHST to
become a cutting machine mechanic specialising
in milling. She is the first woman we come across
on our tour of the metalworking operations at
OHST. For Josephine a technical occupation is
nothing unusual: "A girlfriend of mine is training
to become a manufacturing technician in Rhinow,
and it's quite common nowadays to find women
in technical occupations."

Station 5: **Packaging and Clean Room**

At the entrance of the packaging and clean room section we are stopped by Silvana Pfuhl, who is in charge of operations here: "We try to work in the cleanest possible way in this area. Please put on some overshoes." Cleanliness and strict hygiene regulations characterise the operating area with the most critical process in the company – the final cleaning of implants and instruments: "We have a form that needs to be filled out. If anyone is ill they have to report to me, even if it's only a cold." The clean room is at the heart of packing operations. Here the cleaned implants are packed and prepared for sterilisation. Clean-room packaging and sterilisation turns the workpiece made of metal, plastic or ceramics into an endoprosthesis which can be used directly during the operation. The work done by the staff in this section is similar to the operations of sterilisation assistants in a hospital, says Ms Pfuhl, but so far this is not recognised as an individual occupation: "I come from Premnitz and qualified as an office clerk in Nauen, but as soon as I finished

my training I had the opportunity of working in cleaning operations here. We work to a very high standard, but because of the structure which characterises a family company there are good opportunities for career development and longterm employment here."

The implants and instruments reach the packaging and clean room section after a preliminary ultrasonic cleaning process, which removes any operating materials from the mechanical production facilities, and are then packed in blue containers. "Blue means clean. After cleaning all parts are checked once more for scratches and surface defects, and then they are released to us. We create the product labels and plan the packing and possible assembly in the clean room", is how she describes the process, which has the aim of supplying sterile implants and instruments which are ready for operation. Before the parts enter the clean room

sterile barrier system of an implant

Employee in the clean room

they receive a final wash. "There are separate washing programmes for the different materials - metal, plastic or ceramics. Subsequent to the washing process the machine can only be opened once more in the clean room." In the glass-walled cabin with controlled ambient conditions Silvana Pfuhl and her team carry out a multi-stage process.

There is a strict sharing of responsibilities in the clean room: the first member of the team packs the medical product in the peel bag and carries out any assembly work which has to be done. Products are broken down into their individual parts before cleaning, to make sure that no water remains in any hollows. In accordance with working instructions which Ms Pfuhl draws up with the R&D department, she and her team press polyethylene parts into cups and screw lids on metal cups. Even the second member of the clean-room team no longer touches the product any more, but only labels and peel bags. "The labels here are given a sterilisation dot. This is an indicator which changes after sterilisation from yellow to red." Following this the cleanly packed and labelled products are put in cardboard boxes in the packing section and then sterilised by an external certified service provider. For Silvana Pfuhl and her team the work involved in hygiene is a matter of great responsibility: "You always have to keep in mind that these are products which will be applied inside a human body. They are destined for patients, and maybe I will need one of them myself one day."



Alignment of a part on a measuring machine

A discussion of the importance of standards in the manufacture of endoprosthetics, and the implementation of legal specifications on the way to creating a medical product

Product approval and the certification of medical products are daily routine at OHST. It is the job of quality management to ensure compliance with official specifications and controlled production processes. Chris Schedlo is in charge of this department, while Heike Bookhagen is responsible for regulatory affairs, through which the legal specifications are applied within the company.

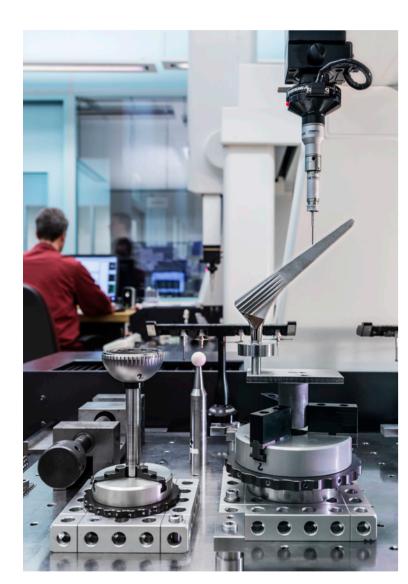
Ms Bookhagen, it was you who set up the quality management operations at OHST.

HEIKE BOOKHAGEN

I was an engineer for precision mechanics at the Rathenower Optischen Werke, but after reunification I took further education in the field of quality assurance and joined quality assurance and joined OHST after an internship here. I was the company's 20th employee and my tasks included order processing and producing labels, as well as obtaining and evaluating product standards. I was then given the task of setting up a quality assurance system. We received our first certification in December 1995. Since then the applicable requirements have grown a great deal and they are still on the increase – it will be very interesting to see how this will develop in future.

CHRIS SCHEDLO

The quality management system has been in existence since 1995, but when I started here we still had a kind of dual structure and our personnel often didn't follow the system. They still sometimes tried to do things outside of the system – because it's faster just to go ahead and do something without documenting it. We made sure this was changed, because simply going ahead and doing things leads to risks. All product defects are due to an error in the process, either as a result of incorrect specifications during development or during implementation in the production process.



Measurement set-up on a 3D coordinate measuring machine

How does quality management function?

It's basically all about structuring processes and ensuring that they can be checked. The more freedom an employee has, the greater the chance that he or she will do something that isn't correct. Quality management removes these freedoms from employees for the purpose of minimising risks. Of course this is difficult to implement. People suddenly find themselves forced to document their operations, to check things and comply with strict specifications. It means a lot of administrative work, especially with a company like ours, which has to comply with a lot of specifications. I apply audits for this purpose, in order to make sure that staff comply with the specifications. In addition I point out weaknesses in the system, which people generally prefer to ignore.

Is this a difficult task from a personal point of view?

When I enter the production area people immediately tend to think: "Looks like we've got a problem somewhere." But it's simply a matter of asking the right questions. I started here as a student and I've got close contacts with the colleagues on the factory floor. When you're on first-name terms it makes things easier. The company's dragon boat team also creates a certain level of solidarity.

HEIKE BOOKHAGEN

In the course of the years we have all grown into a cooperative team within the company, and we can rely on one another. For me it's important to make sure that we make products which are safe for patients, and to ensure that everything we put on the market complies with the relevant standards. Medical products are a challenge, because the applicable standards are changing constantly.

How often do the statutory requirements change?

HEIKE BOOKHAGEN

I make a regular check to see what standards have changed and whether a new draft standard requires action on our part. For example, there are now new specifications relating to the locking test in knee joint implants. I need to draw attention to this when I have an implant tested in the laboratory, in order to make sure that the specifications are complied with. This also applies to our suppliers, for example those who give our products a coating to ensure a good growth of the implant into the bone. On the basis of these specifications Mr Schedlo then draws up a questionnaire for the supplier, with whom we later carry out a quality audit. On the basis of this audit we can then prove that the supplier meets the applicable requirements and applies the coating correctly, for example. This enables us to ensure that the product can be safely implanted in the human body.



CHRIS SCHEDIO

Ms Bookhagen makes sure that the market requirements relating to a product are known. She supplies the specifications for the product, and I make sure they are applied in the production process. As part of quality management operations we also need to recognise whether new specifications could have a negative effect on other processes. A stable process can quickly be destabilised when a routine operating process is disrupted. This is why risk management becomes a central responsibility whenever a change to standards is implemented. The analysis of the risks later forms the basis for a decision on my part relating to whether - as a precaution we make a process safer by providing work instructions.

HEIKE BOOKHAGEN

Records such as test reports, drawings and calculations are all grouped into technical documentation which is checked by our "notified body" – an auditing and certifying body which checks the conformity of medical products. In the end we receive so-called 'design examination certification'.

Is it important to you what kind of products you make?

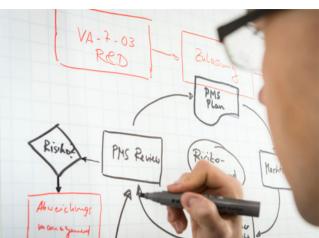
CHRIS SCHEDLO

For me personally implants can be experienced most vividly in the form of complaints. I then see a product which has been removed from someone's body, with remnants of bone still on it, for example. You see that this medical product had once been part of a human body. I then need to decide which departments of our company are affected. Do I go to R&D, to the production technology section, or to the sales department?

Our quality management system helps to avoid product recalls. In spite of this it can









happen – though fortunately this is very rare.

Product recalls as a preventative measure are our last resource – and it leads to a really stressful situation. You've taken so many measures to make sure that everything goes right and then some component simply fails.

The human factor is always involved, as well as pure chance. However, if an implant no longer works correctly the consequences are horrendous, because a follow-up operation has to take place to remove the faulty part, and then replace it with a new implant. This is a major

procedure for the patient, and so we apply all possible means to avoid any loss of function from the very start. If we find that a product fails to meet our quality requirements we recall it as a precaution.

HEIKE BOOKHAGEN

At our company the manufacturing process is monitored and we discover any weak points before product defects can arise. For our customers "Made in Rathenow" represents a seal of quality.



The OHST staff enters its own team in the annual dragon boat race organised by Drachenboot Havelland e.V.. As the "prOHST" dragon paddler with a navigator and drummer, they came in a very creditable second place in the premium class of the 12th Rathenow dragon boat race in 2016.

OHST AG – commitment to the region

OHST Medizintechnik takes its social responsibilities seriously and regularly sponsors social and educational organisations in Rathenow, together with clubs and sporting and cultural activities.

Among others the family firm supports the FSV Optik Rathenow football club and the Havelland dragon boat association, the Rathenow music school, the Horizont children's home in Rathenow-Steckelsdorf, the Spektrum school for the development of children with learning disabilities, Optikpark Rathenow which was opened as part of the 2006 state garden exhibition and the Plan International children's charity. The company also

provides support for the OrthoLoad Club, which was established under the scientific supervision of the Julius Wolff Institute of Berlin's Charité University Hospital and promotes a dialogue between prestigious implant producers and scientific, medical and industrial partners with the aim of finding solutions together for the improvement of orthopaedic implants and for dealing with problems in joint replacement.

OHST Medizintechnik takes its social responsibilities seriously The development of a knee system within the OHST R&D department

Today's prosthetic knee joints are hardly comparable with the ivory hinges which were implanted into patients around 1890. For example they consist of polished metals and plastics, enable more complex movements and sporting activities, and the insertion of an artificial knee joint is a routine procedure in orthopaedic and accident emergency surgery. For the patient the insertion of an implant often ends a period of serious pain and restricted movement.

OHST invests 9% of its overall turnover in research and development. It often takes years for an ingenious design to be approved as a medical product. New developments for the most part adapt the technological standard already available on the market. They generally consist of modifications of existing systems, such as a new surface coating. "We operate in a highly conservative industry. Our joint systems and tools are developed on a step-by-step basis," explains Board Member for Markets Stephan Dunke in describing the company's strategy. New medical products are created by teams made up of engineers and the medical staff who apply the products in practice. The surgeons themselves define what they require of the products, evaluate the state of the research, and support the

clinical assessment. Complaints from customers technician, a combination of engineering science aspects with proven benefits, how implants can and those who apply the products are also and medicine. In Rathenow he developed the

Workshop with artificial bones

integrated into further developments in the form of 'post market surveillance', an appraisal of the effectiveness of medical products. "We increase safety for patients by identifying any weak points as early as the development process."

The future of knee joint prosthetics is already being planned in the R&D department at OHST. Torsten Schleuß is a qualified medical

ZEN knee system for the market and is now fine-tuning its individual components: "In the spring of 2009, when the project was launched in cooperation with a French customer, OHST was not yet producing a knee system under its own name. In 2012 we started production of the initial parts." For the ZEN knee project existing systems were analysed for any weak points, together with an assessment of those

best be adapted to the human body, and how the durability of components can be assured. The relevant findings all flowed into the ZEN knee system and the design of the related instruments, in other words all the tools required for implanting the artificial knee joint. To ensure reliable and rapid use their function needs to be immediately identifiable. Silicon handles ensure ease of grip, while coloured markings identify related instruments and their connection with the 38 | Engineers, surgeons and Zen Buddhism

implant. Monolite trays made of premium-quality stainless steel serve for the transport, cleaning and sterilisation of the instruments. There are good reasons for all the work that goes into developing them: "The doctor holds the implant itself for maybe six minutes, but the instruments are in use during the entire surgery, which can take between one and two hours."

The surgical instruments are supplied with every ZEN knee, together with surgical technique for doctors informing them when the prosthetic part can and can't be used, how it is to be inserted and what side effects may occur. For optimum adaptation to the patient's physical circumstances it enables the individual steps of the operation to be checked as they are implemented, and if necessary the return to a reliable starting point after every phase: "We have developed a highly

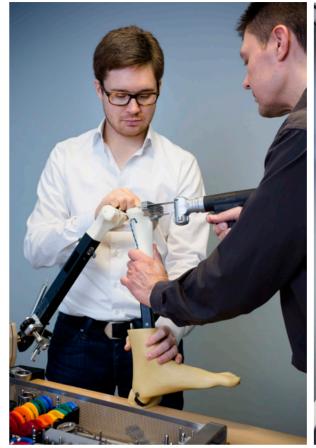
Office location for R&D



safe method, even if it may not be the simplest. But it's reproducible and very precise in its end results."

Schleuß describes what connects the design to Zen - the Japanese form of Buddhism. "The Buddhist philosophy in the ZEN knee and the related operating technique is represented by the adaptation of the operating method and the components to the patient. Our intervention in the sinews and muscles is as minimal as possible. This enables an ideal fit and freedom from pain. The components come in various sizes, in line with the physical dimensions of the patient." The innovatively controlled patella of the ZEN knee system avoids the pain which can arise if a lack of stabilising sinews allows the patella to exert pressure on the thigh bone. The production tolerances are also planned with precision: "During the operation doctors are not working under laboratory conditions. A certain amount of play among the individual components makes sure sure that everything can move freely. The high precision level of our production operations means that with the ZEN knee any friction is minimal, and we have also received positive feedback relating to accuracy of fit."

New operating techniques are not developed exclusively on the drawing board: "Our R&D section works with a number of hospitals in order to acquire a better understanding of the biomechanics involved and the loads which implants have to bear." Occasionally the engineers act as observers during an operation and watch how the surgeons do their job. "Our developers participate in the operations in





Philipp Knöpfel and Torsten Schleuß during a development work-shop

order to study problems, operating procedures and techniques in detail, so that they can adapt our products to them and optimise them accordingly." It enables them to get a feel for the practical application of the implants and instruments: "In the Zen knee system we carried out cadaver workshops in Paris with the newly developed instruments and the entire team. That's the first moment where you come into close contact with the subsequent reality. This is where you see whether everything is working and fits – far from the virtual reality of the computer." The ZEN knee has been a success on the market for four years now.

We increase safety for patients by identifying any weak points early in the developmemnt process.

A personal contact for every requirement

Talking about customer relationships and the special features of producing medical products

What OHST offers in the field of endoprosthetics ranges from development via approval and production right across to sterile packing. The contact partners in the sales division provide the interface with the customer – right from the initial idea to the marketable finished product. Within the OHST Sales Team Gerd Hielscher is responsible for customers in the German-speaking regions.

At OHST does every customer have a personal contact to take care of the customer's concerns?

We know the background of our customers, visit them in person and invite them to trade fairs. A personal contact means reliable customer support and avoids any loss of important information.

What role does Rathenow play in contact with your customers?

Many of them are surprised that we're an hour's

drive from the nearest motorway. But this enables them to get to know the wonderful surroundings of Rathenow, together with the many lakes and waterways or the Havel, where I spend a lot of time fishing.

What differentiates you from your competitors?

We know from long experience what is technically feasible, and can provide forecasts relating to market developments. Our implants – some of which have been tried and tested on the market for 30 years now – are state of the art. Over the years we have developed a

comprehensive understanding of the demands which our customers face. This enables us to support them on all required levels – whether it's with comprehensive process know-how or professional consulting on new operating techniques. Our customers rely on our expertise and technical skills. One member of our team originated in R&D, while I myself was production manager for many years and know our production processes inside out. We stay in close touch with the latest science via our R&D section, and keep up to date with the latest research.

What does this know-how mean for your customers?

The high level of reliability of our team enables our customers to avoid development experiments, and speeds up coordination processes in everyday operations. By bringing together the know-how of the individual sections we are in a position to fulfil orders reliably and fast from start to finish. Our core business is set up for the long term. We generate a large part of our sales from long-term business relationships and from the targeted design and ongoing development of products.

Has the change from family firm to industrial corporation changed your customer relationships?

Our customers have always had their own individual contact partner. Changes are due



How important is a personal relationship for long-term business relations?

complex.

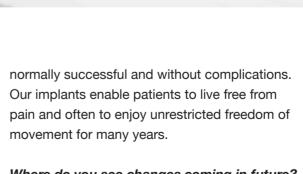
The business today is increasingly international in its nature. Our Board Member for Markets visits customers worldwide, but daily customer contacts are the responsibility of the sales department. Domestically our industry is a fairly small one – for example I have a customer whom I have come across for the fourth time at a

different company. In this industry we meet one another regularly and share experiences. Our good reputation on the market is what attracts

What do implants mean to you?

potential customers.

ur products ensure patient satisfaction. Patients suffering from arthrosis in particular often experience serious pain. However, operations are



Where do you see changes coming in future?

We are currently working on refining our implants and on improved adaptability to the individual body. Individual components are produced

in ten different sizes, and we are testing new materials. The aim is to shorten operating times, enabling 3D measurement of patients, and the development of patient-specific cutting blocks. The implants of the future will function in the same way as the current ones, but the quality of life of patients will improve more and more.



On-site product presentation

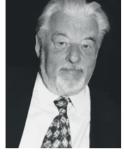
44 OHST turns 80

OHST turns 80 30 years of medical devices

1949 -

1989





Willi Ohst 1897-1947

Wolfgang Ohst 1928-2001

Founded in Rathenow by toolmaker Willi Ohst in 1937, OHST AG remains family-owned and managed to the present day. Initially the company manufactured tools for the local optical industry, followed later by paper testing machines for the GDR's export market. In 1985 the first acetabular cups were developed in coordination with Berlin's Charité Hospital, with regular production starting in 1987 followed in the Nineties by full concentration on medical products. In subsequent years the company significantly expanded its development, production and sterile packing of joint implants and operating instruments. The Ohst family invested consistently in the latest technology, above all for the production of hip and knee joints. Today the successful mid-sized company with its workforce of 140 is managed by the great-grandsons of the company's founder. In contract manufacturing OHST Medizintechnik offers the full spectrum of operations, from development via production to the shipping of endoprostheses in sterile packaging.

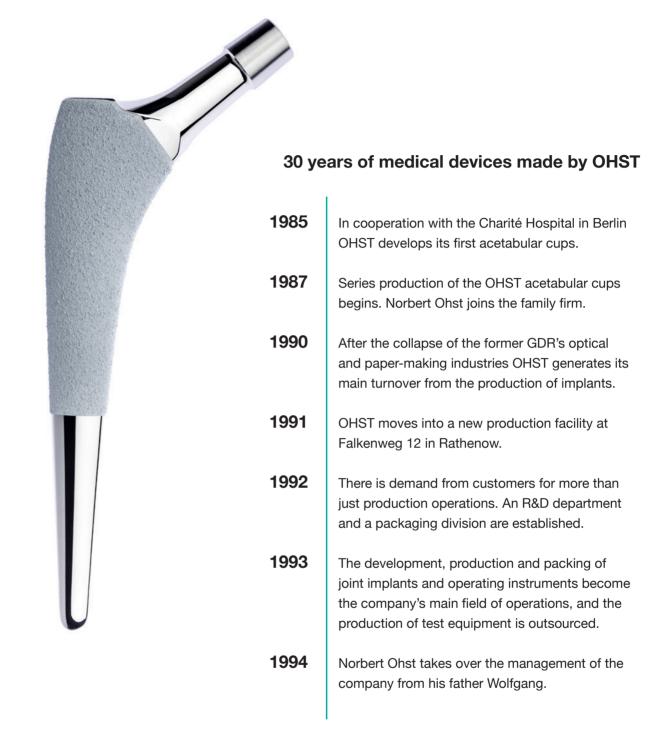
Precision engineering from Rathenow since 1937

Willi Ohst, born in Rathenow in 1897 as the son of Friedrich Ohst, did his apprenticeship as a toolmaker with the Altstädtische Optische Industrieanstalt Nitsche & Günther, obtained his master craftsman's certificate in Brandenburg and journeyman's qualification from the Berlin Chamber of Trades, and worked from 1922 to 1936 as a foreman at Wiesinger & Co, which became "Rathenower Optische Fabrik Alpira" in 1924.

Master toolmaker Willi Ohst founds his own workshop for the production of tooling for the optical industry in Rathenow.

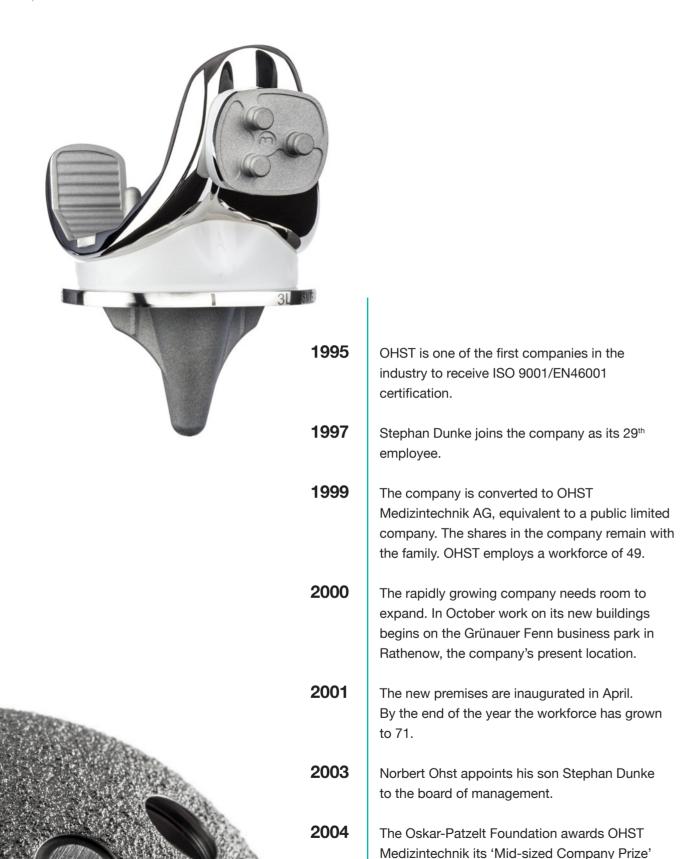
Willi Ohst dies at the age of 50 and his son
Wolfgang Ohst receives special permission to
take over the company at the youthful age of 19.

In addition to the production of equipment and small machinery for the optical industry, OHST manufactures testing devices for the paper making industry (for checking the fibre thickness and cellulose content of the raw paper mixture). Because its testing machinery was sold to non-socialist countries OHST earned foreign exchange for the GDR and was therefore allowed to continue operations as a private company.





46 | **OHST turns 80** OHST turns 80 | 47



for continuous development, innovation and

closeness to the customer.

2005 A new factory building increases the production area to 4,100 m². The quality management system is switched to the process-oriented ISO 13485:2003 standard. Ongoing investment and expansion of production capacity with new machinery such as ultrasonic cleaning technology. The number of staff is 115. 2006 A subsidiary for the production of casting products is established at Falkenweg 12 in Rathenow. 2008 Norbert Ohst receives the "Premier Finalist" badge of honour from the Oskar-Patzelt Foundation for positive continuity in the development of his business. Norbert Ohst's son Sebastian Sturm joins the company. 2011

OHST receives the IF-Product Design Award for the development of its Monolite Tray System.

2013 Sebastian Sturm becomes Board Member for Production

2016 Norbert Ohst retires and switches from the management board to the supervisory board.

2017

In two shifts a workforce of 140 produces the components for 18,000 hip and 16,000 knee joints per year, and annually 30,000 to 40,000 patients are provided with OHST implants.





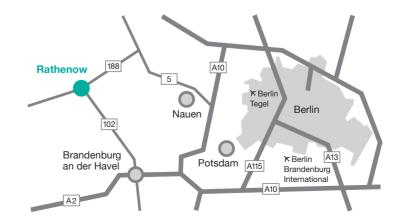
HOW TO CONTACT US:

OHST Medizintechnik AG Grünauer Fenn 3

14712 Rathenow Germany

Tel +49 (0) 3385 5420 0 Fax +49 (0) 3385 5420 99

Email info@ohst.de URL www.ohst.de



Legal notice

Concept and design

Agentur BAR M

Fabian Hickethier,

Inga Attrot (graphics) und

Steffy Eckers (graphics),

Justus Wenke (texts),

Burkhard Peter (photos),

Pages 5, 6, 7, 44: OHST Archiv

Page 34: Jürgen Ohlwein

Printers

BLOCH & CO Offsetdruckerei

Disclaimer

No liability or guarantee is assumed for the timeliness, accuracy and completeness of the information provided in this publication. Any liability for material or immaterial damages caused by the use of this information is excluded.

50000701 Rev.001 2017-03

1 9 8 7