

The image features the Tracoe logo centered on a white background. The logo consists of the word "TRACOE" in a bold, black, sans-serif font, followed by a registered trademark symbol (®). To the right of the text is a blue swoosh graphic that curves upwards and to the right. The background is populated with numerous light gray line-art icons of various medical devices, including endoscopes, probes, and surgical instruments. Some of these icons include the word "TRACOE" or a stylized orange slice logo, which is a secondary brand mark for the company. The icons are scattered around the central logo, creating a collage effect.

**TRACOE®**

**TRACOE®** 



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Yesterday, today, tomorrow

### **Legal Notice**

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# QUALITY BY

# PEOPLE

## 60 years of TRACOE medical, 60 years of future

Ten years have now passed since we celebrated a company history spanning half a century with our book on the 50th anniversary of TRACOE. So you may well be wondering, and rightly so, why you are holding a copy hot off the press – exactly a decade later. The answer is as short as it is simple: because since then the company has grown so rapidly that this decade alone could fill a book. Since 2008 we have achieved no less than to set the course for a strong future. This includes shortening the innovation cycles, strengthening change management capabilities on all levels, reorientation of quality management, modernisations in production and logistics, several key products brought to market and, of course, the continuous optimisation of our distribution. In brief: we have left no stone unturned and adapted all the structures and processes to the new dimension, including against the background of international expansion. However, there is one thing we have not changed – the steadfast commitment to our values as important pillars of TRACOE medical. We want to improve the quality of life for patients, contribute to successful treatment by medical personnel, display humanity and honesty towards our customers, suppliers, partners and employees, and achieve stable and sustainable growth. To this end, we are focussing on premium products made in Germany, on quality, made by people for people. Yesterday, today – and, of course, also in the future.

Stephan Köhler

Dr. Thomas Jurisch

1958–1972

## THE BEGINNINGS OF TRACOE

*It is tantamount to the turn of an era: in 1958 the engineer Rudolf Köhler developed an innovative tracheostomy tube made of transparent, flexible PVC which replaced the rigid metal tubes and so improved the situation for patients tremendously. But this was no easy matter, as a great deal of specialist expertise and precision is required to process the plastic components.*

*Rudolf Köhler invented a unique procedure whereby the cannula can be securely bonded with the neck flange which is just two millimetres thick. The tubes were initially produced using outworkers. Pfau-Wanfried, a subsidiary of B. Braun Melsungen AG, took over distribution. And, in fact, the new plastic tube gained increasing acceptance on the market by comparison with the metal tubes, and the company grew and flourished. However the future of the company became very uncertain when its founder Rudolf Köhler died suddenly in 1972.*

# A GROUND-BREAKING INVENTION

*Rudolf Köhler ca. 1930*



### **The young founder, Rudolf Köhler**

Even the largest companies all started with an idea – and just as with many companies, TRACOE's history also had its origins long before its official founding in 1972. It was the summer of 1955: in the Institute of Physiology's metrology laboratory at the Johannes Gutenberg University, Mainz, Rudolf Köhler tinkered with measuring instruments for medical research; he was a passionate inventor and always on the lookout for an even better solution, for something to make life easier for people.

*Rigid metal tube with obvious signs of use ca. 1958*



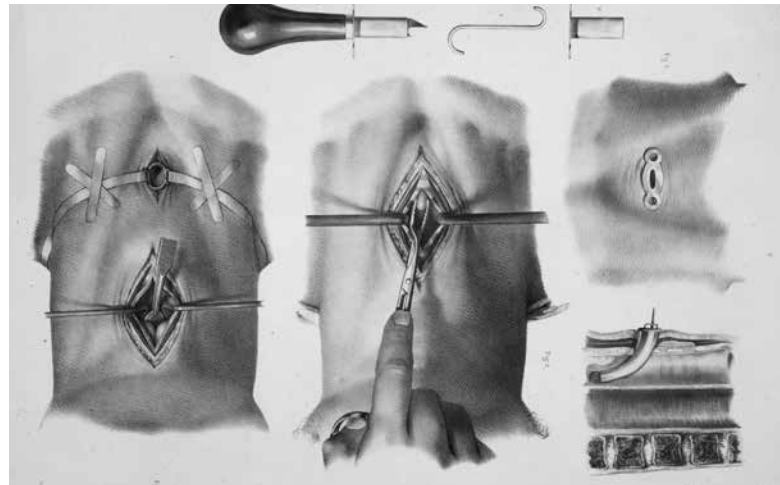
Along this journey, after his *Abitur* (higher education entrance examination), this son of a mayor, born in 1902 in Gladenbach near Marburg, first completed an apprenticeship as a precision engineer. He met Hertha Lose, who was to become his wife, when he was technical director of a factory in Pützchen near Bonn, and their first son Wolfgang was born in 1930. During the war, however, the family lived in Poznan, where they had two more children. When the war ended, the family fled to Marburg, where Rudolf Köhler soon found a livelihood at the university's Institute of Physiology. The family ultimately moved to Mainz in 1948. In this city on the Rhine, Köhler was made head of the Institute of Physiology's metrology laboratory at the Johannes Gutenberg University, Mainz.

### The desire to help

It was in the summer of 1955 when he learned from physicians in the ENT department of the story of a patient whose larynx had been removed. The trachea was permanently open due to a so-called tracheostoma on his neck. Though operations such as these did indeed save the patients' lives, they considerably impaired their quality of life as, at that time, metal tubes made of silver kept the tracheostoma open. They made it possible to breathe, but the rigid material caused pressure points in the trachea and the sharp edges of the tubes led to recurrent painful bleeding and inflammation. Rudolf Köhler soon became convinced that there had to be a more patient-friendly solution.

### Tracheotomy past and present

Although absolutely commonplace in modern hospitals today, the field of tracheostomy was little researched until well into the 20<sup>th</sup> century and a veritable medical adventure. It was performed for the first time in the 16<sup>th</sup> century by the physicians Fabricius from Padua and Ambroise Paré, but only used more frequently from the 19<sup>th</sup> century onwards, thanks to the first scientific findings on respiratory disease and the open surgical technique of tracheotomy. Further decades passed until in the mid-1950s doctors first attempted to



*The beginnings of modern tracheostomy: lithograph of a tracheostomy from 1831*

perform a percutaneous tracheostomy, in other words, a minimally invasive method. Yet the traditional tracheotomy of the previous century remained the norm for a long time in hospital routine and it was not until the mid-1990s that it was almost completely superseded by percutaneous tracheostomy. Today it is commonplace for operations and intensive care, and it has been continually developed and improved both in hygiene and technical implementation in the past years.

### Initial attempts

However research still had a long way to go in 1955. The patient of whom Köhler had heard complained in particular about the rigidity of the material, making any movement of the head painful. The prospect of having to live permanently with a metal

tube caused the patient to despair – and left Köhler pondering further. He quickly realised that only a tube made of a completely different material could offer the patient real relief. Rudolf Köhler persevered in his search for a solution and made many attempts, which unfortunately were unsuccessful. First he wanted to cover the sharp edges of the metal tube with a plastic coating, but the bonding between metal and plastic was not stable enough. Experiments with plexiglass were more promising. It was similar to metal in its rigidity, but had many other advantages: it was transparent, light, and had no sharp edges. So Rudolf Köhler initially made a plexiglass tube for the patient. Soon more patients were asking for plexiglass tracheostomy tubes and demand increased. Was this the solution?

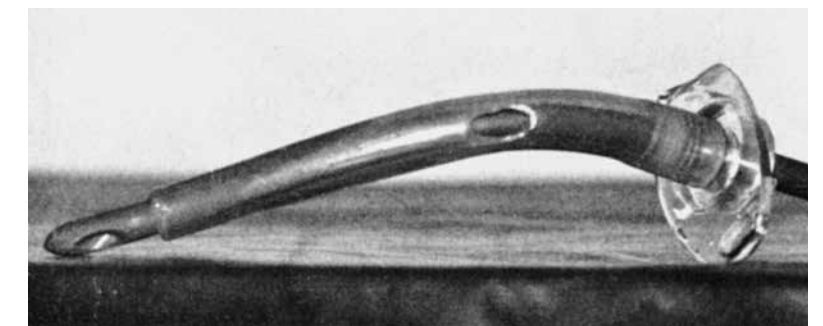
No, because the physicians remained suspicious, as they feared the tubes might break or splinter under the pressure of the trachea. Also, each individual tube first needed to be approved by the competent health insurance fund. And even Rudolf Köhler was not yet satisfied, as the main problems persisted. Plexiglass was also rigid and caused pain. So Rudolf Köhler continued to experiment and went in search of a soft material that was flexible but nevertheless stable enough. This was the only way that injuries could be avoided

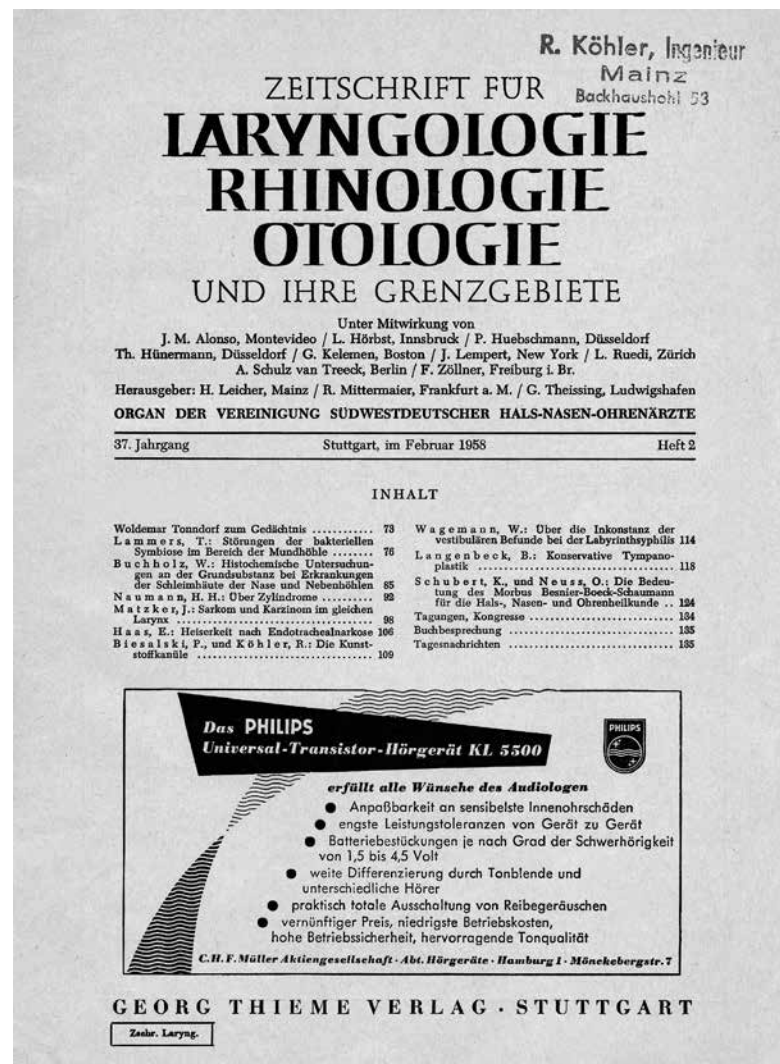
and patients who had been dependent on tubes for a lengthy period, or even all their lives, would finally have a better quality of life again. From December 1955 onwards, Köhler persistently exchanged information with the patients concerned, speaking with them often for hours – and finally produced a prototype of the “perfect tube”.

### Plastic – the material of choice

And this was the breakthrough. He came up with the plastic polyvinyl chloride (PVC) which was perfect for a flexible tracheostomy tube. It could be shaped at high temperatures yet was stable enough for the pressure in the trachea. The miracle plastic, which had been invented at the beginning of the 20<sup>th</sup> century, experienced a real boom after the Second World War and found increasing acceptance in many areas of life, including in medicine. Here, for example, it was used for the production of indwelling catheters in neonatal medicine.

*PVC cannula with guide tube for insertion into the trachea*





In 1958 Rudolf Köhler presents his invention in the February edition of the journal "Laryngologie, Rhinologie, Otologie"

Rudolf Köhler quickly recognised the advantages of PVC and created a tracheostomy tube with both cannula and flange made of PVC. He bonded the two elements using an adhesive he had developed himself that was stable and reliable. Köhler's new tubes were light, flexible, and for the first time offered patients a high level of wearer comfort. The PVC was tissue-friendly and the soft edges and smooth walls greatly reduced the risk of injuries. Physicians and nursing staff were enthusiastic, also because the transparent tubes were easier to change and clean. In addition, the PVC tubes did not interfere with radiological examinations or radiotherapy. Secretion also decreased significantly with the new tubes, particularly in the case of neonates and infants. Furthermore, at that time production of the tubes was already more cost-effective than that of metal tubes, and allowed a range of custom-made devices with individual length and bending angle. So Köhler soon added extra-long tubes with inner cannulas to the range – metal tubes had only been possible without inner cannulas due to the 90-degree angle of the tube.

Yet for all his success, production of the tubes remained merely a "sideline" for Rudolf Köhler for a long time. During the day he continued his regular activity at

Mainz University, only attending to production of the tubes in the evenings and at weekends.

In 1957 Rudolf Köhler met Peter Biesalski, an encounter that was to be significant for the development of the company: the head of the ENT department at the University of Mainz supplied his patients with Köhler's tubes and was able to provide the producer with important information from clinical practice. Not least for this reason, Biesalski ultimately became Köhler's adviser under contract – and the two of them made a good team. Together they published the first scientific paper on the new tracheostomy tube in the "Zeitschrift für Laryngologie, Rhinologie, Otologie und ihre Grenzgebiete" in February 1958. In the paper they explained in detail the advantages of the PVC cannula as compared with the rival products made of metal. An article that was to bring many changes, as a strong partner for further marketing also suddenly appeared.

Several weeks after the publication, Pfau-Wanfried, a subsidiary of B. Braun Melsungen AG, offered to include the product exclusively in its programme. And Eastern Europe was also literally crazy about the tubes. Aesculap, another holding company of B. Braun Melsungen AG,

took on the distribution. With hindsight, the specialist publication and the distribution agreement with Pfau-Wanfried in 1958 can be seen as a significant key to the success of the enterprise – and as the birth of TRACOE in its present form.

Yet as well as the Köhler/Biesalski team got on at the outset, conflicts between the two entrepreneurs arose just as quickly. Finally the cooperation came to an end – and the two colleagues became rivals.

Biesalski developed his own plastic tracheostomy tubes with the firm Rüschi; these tubes were also used increasingly in hospitals in subsequent years – the so-called "Kanüle nach Biesalski" (Biesalski tube). Although a second supplier was now offering flexible tracheostomy tubes on the German market, demand for Köhler's product continued to increase. The breakthrough had succeeded – the tube had made its mark as a quality product in the niche market of tracheostomy.

# DEEP FRIENDSHIP

## Encounter with consequences

Meeting the physician Franz Waldeck, who at that time was employed as an assistant and later senior assistant at the Institute of Physiology, was to provide a more enduring and considerably more sustainable cooperation for Köhler than he had experienced with Biesalski. The two got along with each other right from the start and around 1960 formed such a close friendship that they often sat together in Köhler's office until late at night, forgetting the time amid long discussions. At the time, neither Rudolf Köhler nor Franz Waldeck realised how much this friendship was to affect their own lives and the lives of their families, for later – in 1963 – at only 28 years of age, the Frankenthal-born physician was promoted to professor and in 1966 began his career with the Boehringer pharmaceuticals group. From 1977 onwards, as a member of management, he was responsible for worldwide research and development. He remained loyal to his close friend Rudolf Köhler throughout his entire professional career.



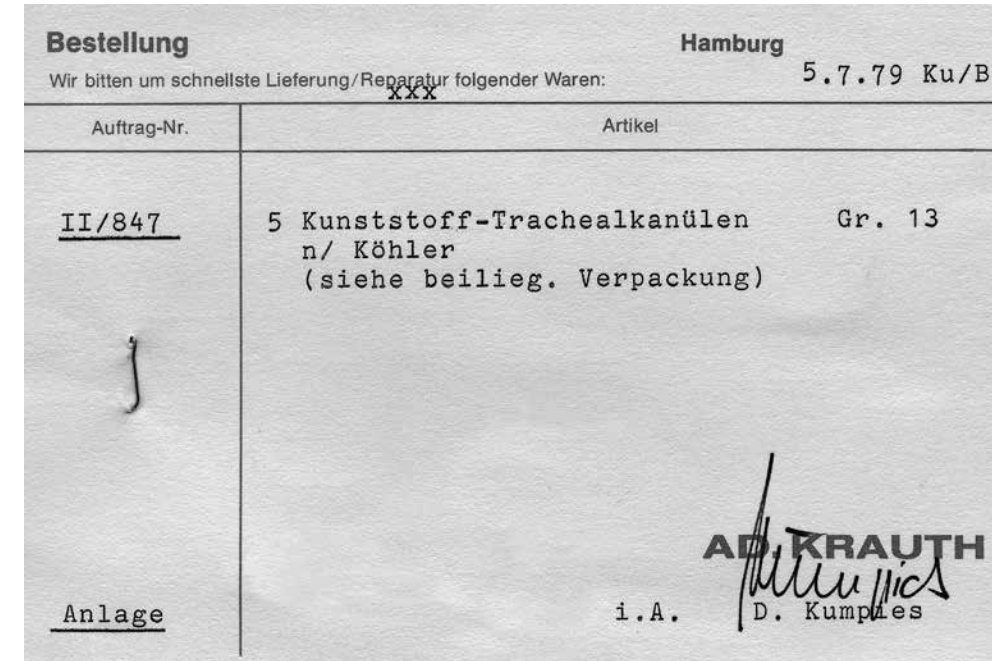
Professor Franz Waldeck MD

## Business flourishes

During the 1960s Rudolf Köhler had more and more orders and soon he was no longer able to cope with the work alone. His first employee was Karl Beckhaus, a gifted young man whom he met in 1964 in the Master Craftsman (*Meisterprüfung*) Examination Board of the Guild of Precision Engineers (*FeinmechanikerInnung*). Beckhaus became Köhler's "right-hand man" and after 1965 made tube components for him as a sideline, soon even assisted by his wife. However, the tubes were still assembled by Köhler himself. When he had glued the flange and cannula intricately by hand, he sent them to the distributor Pfau-Wanfried. Thanks to the support from the industrious Beckhaus couple, Rudolf Köhler was always able to deliver within a matter of days – even with ever-increasing demand.

Rudolf Köhler finally retired officially in 1967 and at last had the time to concentrate totally on the production of tracheostomy tubes. This was also necessary because Pfau-Wanfried were now ordering so many tubes that, in addition to the Beckhauses, Franz Waldeck's stepson and his partner were also employed.

Mr and Mrs Beckhaus



Order from A.D. Krauth for five tubes in 1979

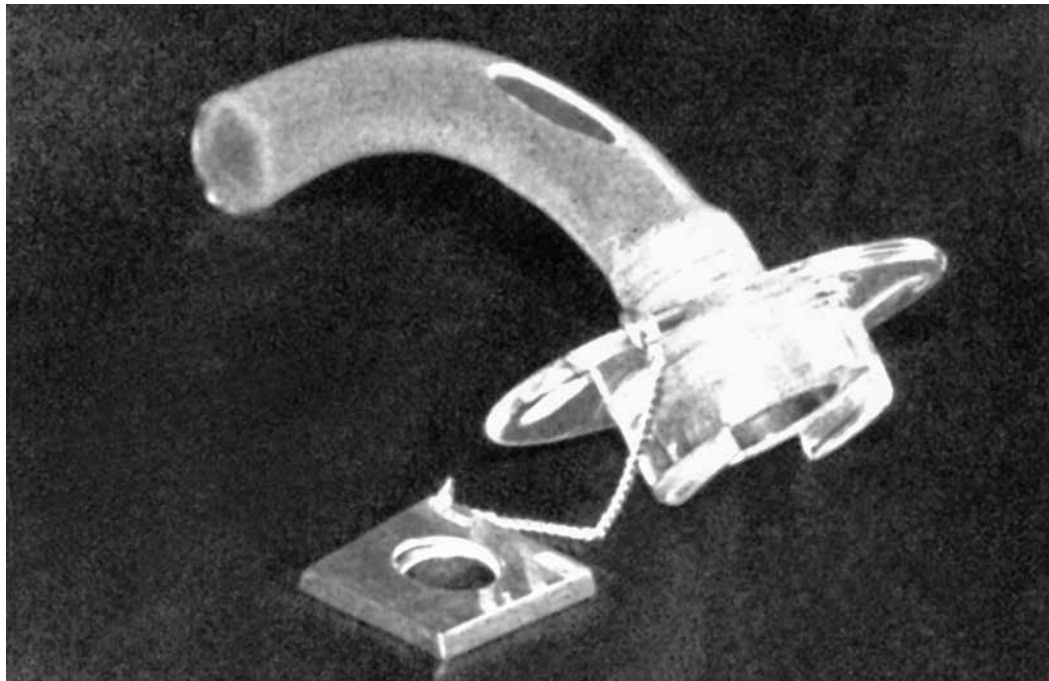




### Death at an early age

While the business with tracheostomy tubes grew and grew, Rudolf Köhler's health became worse and worse. A heavy smoker all his life, he now had lung cancer and without any prospect of recovery. But as no one was able to make the tubes completely – production of the adhesive in particular was a secret that was in danger of being lost – the entire business model began to falter. So Köhler wrote the formulation down by hand on a piece of paper, because nothing concerned him more than the fear that the manufacture of the PVC tracheostomy tubes for the good of the patients might not be able to continue. A fear that he took with him to the grave. When Rudolf Köhler died suddenly in a Wiesbaden hospital in 1972, it was completely uncertain as to how production of the tubes was now to continue.

*Köhler's invention, today called TRACOE comfort*



## TRACOE *comfort* – *comfort* for the patient

TRACOE's history began in 1958 with the PVC tracheostomy tube – which until this day is still a key component of the product range for long-term use in the HomeCare sector.

Its excellent anatomical fit and surface properties offer greater user comfort than the silver tubes that had been the market leaders until this time. The transparent material is cosmetically acceptable and easy to clean. In addition, PVC is radiolucent, so that the patient can still wear the tube during X-ray procedures or radiotherapy.

Since the introduction of TRACOE *twist* in 1996, the tubes have been supplied under the name of TRACOE *comfort* in various sizes and designs tailored specifically to the needs of the patient. The name says it all: for patients, who have to wear a tube permanently, the experience should be made as comfortable as possible. The tubes are still hand-crafted to this day.

1972–1990

## FOUNDING OF TRACOE GMBH

*It had to continue. After the sudden death of Rudolf Köhler in 1972, his son Dr. Wolfgang Köhler inherited protection of the utility model for the tracheostomy tubes. Then everything happened very quickly. Together with Professor Franz Waldeck and his own wife he founded TRACOE Gesellschaft für medizinische Bedarfsgegenstände mbH in the same year. The two of them shared the responsibilities – Waldeck took care of production and development, Wolfgang Köhler assumed the management of the company and was responsible for distribution and marketing. He built up an international network of distribution partners – and in fact, after the initial difficult times in the 1980s, it was all systems go for TRACOE. But then Wolfgang Köhler died suddenly in 1990.*

## FROM THE IDEA TO THE COMPANY

### **TRACOE GmbH: The birth of a company**

The death of Rudolf Köhler, the guiding spirit, in 1972 was an incisive turning point, because suddenly it was completely uncertain as to how production of the tracheostomy tubes was to continue. In Rudolf Köhler's workshop only a few orders from Pfau-Wanfried were found ready for delivery. There was nothing more in stock. Was this to be the legacy of the enterprise? And who was to further develop the company in future? Rudolf Köhler had built up the business as a sideline and Waldeck had a brilliant career at Boehringer Ingelheim. He couldn't possibly take over the business alone. Suddenly everything depended on Wolfgang Köhler, Rudolf Köhler's eldest son. He had indeed inherited the utility model protection for the tubes, but had quite different plans of his own.



*Dr. Wolfgang Köhler*

### Back to square one

Dr. Wolfgang Köhler, born in 1930, had studied law in Mainz, Hamburg and Berlin and gained a doctorate. After being admitted to the bar as a lawyer, after 1960 he initially worked for a Frankfurt bank. He had married Karla Hünemörder in 1956, and the happy couple became the proud parents of daughters Julia and Catharina in 1961 and 1962. However, in 1965 Köhler and his wife suffered a cruel stroke of fate – the premature death of their beloved eldest daughter Julia. A change of scenery was needed. That same year Köhler moved to Zurich as CFO of Dow Chemical, and years later to the chemical giant's headquarters in Michigan (USA). Then in 1967 their son Stephan was born. A year later, the family moved to New York City where Köhler signed a contract with Morgan Guaranty.

At a young age, Wolfgang Köhler could already look back on an impressive career and was well on the way to developing it further with international banks or the financial management of large conglomerates. At this point, health problems unexpectedly thwarted his plans in the early 1970s. In 1971 he finally returned to Frankfurt with his family and together with his wife he planned a fresh start – but in the following year his father Rudolf died.



*A private moment: Dr. Wolfgang Köhler with his children Catharina and Stephan*

Franz Waldeck then approached Wolfgang Köhler, who had just inherited the utility model patent, with a surprising plan. He proposed that they formed a company together for the production and distribution of tracheostomy tubes. Waldeck reminded him of his father's ardent wish to continue the production of tubes and in so doing to offer many people a better quality of life. As a successful manager at Boehringer, Waldeck was not able to manage another company alongside but thought it feasible for him to attend to the production and development of products as an adviser. The plan: Dr. Wolfgang Köhler was to manage the company and organise distribution and the development of new markets. After several days' consideration and encouraged by his wife Karla, who assured him of her full support, Wolfgang Köhler finally accepted in April 1972. There was nothing more standing in the way of founding the company.

And in fact things started moving very quickly: "TRACOE Gesellschaft für medizinische Bedarfsgegenstände mbH" was founded on 1 May 1972 and it was registered on 17 August 1972. The name of the new company was programme: TRA stands for the product, the tracheostomy tube, and COE for Köhler, the name of the inventor family. Dr. Wolfgang Köhler

became managing director, while Franz Waldeck supported the newly-formed company in a consultative capacity. The articles of association of 17 July 1972 were drafted by Karla Köhler herself. The same year this successful lawyer became a partner in the Frankfurt law firm Pünder, Volhard und Weber – today part of the international and world-renowned law firm Clifford Chance.

*Letterhead from 1975*

tracoe gesellschaft  
für medizinische bedarfsgegenstände mbh.

6367 Karben 2  
Am Schloß 20  
☎ 0 60 39 - 4 15 00

4. 8. 1975

# COLD START WITH COMPLICATIONS

## Difficult legacy, heavy responsibility

The idea was born but Wolfgang Köhler and Franz Waldeck had a long, stony road ahead before achieving realisation. Although the tracheostomy tubes had already been produced and marketed for many years, the company really had to start from scratch when it was first founded in 1972. Wolfgang Köhler and his wife were compelled to commit themselves far beyond the company boundaries. The company director set up the first TRACOE office in his own home, as there were no business premises as yet. His wife Karla, who at this point was actually working at full capacity in her main profession, processed orders and wrote invoices for TRACOE every evening. Twice a week, a former employee of Wolfgang Köhler came to her rescue.

But there were huge obstacles to overcome, particularly in the core business of the company. When he was alive, Rudolf Köhler had not shared his knowledge of tube production with his son. He was the only one who had the necessary expertise for the manufacture of the products. So the greatest challenge for the two young entrepreneurs was how to manufacture the tubes in the same quality and deliver them to the existing customers reliably and promptly. In fact, Karl Beckhaus and the other part-time staff knew how the individual product components were made but until then had not completely assembled a single tracheostomy tube. But Waldeck and Beckhaus had no choice as the orders and bookings from Pfau-Wanfried were piling up. They had to get

production going – and of a quality that met the satisfaction of the customers and patients.

Easier said than done: at first complaints and returns increased – flanges fitted too loosely, the tubes were too soft or the inner cannula was too tight. But the staff at TRACOE GmbH refused to give up and tirelessly continued to develop their products. Feedback from customers and patients helped them to continuously improve the tubes and Karl Beckhaus quickly became familiar with the manufacture of the medical devices.

## The company on the brink

When they had overcome the worst of the difficulties and TRACOE's core craftsmanship prevailed, just as in the time of its creator, the next problem was already on the horizon. The distribution partner Pfau-Wanfried submitted lots of orders just as before. In 1973, however, it became evident during negotiations to extend the framework contract that Pfau-Wanfried wanted to take over the production of the tubes themselves. The distribution partner demanded at least exclusive distribution rights yet could not simultaneously guarantee a sufficient purchase volume. Köhler and Waldeck did not want to be tied to just one distribution partner. The conflicts of



Packaging of tracheostomy tubes from the 1970s

First head office of TRACOE GmbH. In the Köhlers' home.



### On the offensive

But the two company founders refused to allow the problems to throw them off course – on the contrary – now they really went on the offensive. First, sales were turned inside out and organised domestically via pharmacies and specialist health-care retailers. Wolfgang Köhler, who, as a lawyer and former banker, obviously had hardly any experience and even less any contacts within the industry, had effectively been thrown in at the deep end. He travelled to distributors and pharmacists all over Germany, and talked to countless physicians, representatives of the trade press, and also patients. Little by little, Köhler became more familiar with market analyses and customer needs, and now was also developing the first brochures and packaging to raise awareness of the company and, above all, the product. The many specialist articles authored by Professor Waldeck for trade journals also served precisely this purpose, as did the advertisements in which the young company now invested massively. TRACOE also launched an advertising campaign for direct selling in Germany, France, Holland, Belgium, Sweden, and Denmark – and made their first contacts in the USA.

#### Gespräch mit Dr. Wolfgang Köhler, Gesellschafter Geschäftsführer der TRACOE GmbH

**AM:** Dem Handelsregister können wir entnehmen, daß Sie kürzlich Ihr Kapital von DM 20000 auf DM 50000, voll eingezahlt, erhöht haben. Was hat Sie dazu veranlaßt?

**Dr. K.:** Seit vielen Jahren steigen unsere Umsätze im In- und Ausland erheblich. Das zwingt uns dazu, größere Vorräte an Rohmaterialien sowie an Halb- und Fertigprodukten zu halten und macht es natürlich erforderlich, eine entsprechende Liquiditätsvorsorge zutreffen.

**AM:** Welche Gründe haben Sie noch für eine so umfangreiche Lagerhaltung?

**Dr. K.:** Sie ergibt sich aus der Notwendigkeit, im Interesse des Patienten stets sofort liefern zu können.

**AM:** Wie kamen Sie auf den Namen TRACOE®?

**Dr. K.:** Hierzu will ich Ihnen ein wenig die Geschichte der Gesellschaft und ihrer Produkte erläutern.

Einige unserer Kanülen werden bereits seit mehr als 20 Jahren hergestellt und sind in der wissenschaftlichen Fachliteratur – erstmalig 1958 – erwähnt. Bis Anfang der 70er Jahre wurden unsere flexiblen Kanülen von der Firma B. Braun Melsungen AG im In- und Ausland und auch heute noch in osteuropäischen Ländern von der Firma Aesculap, einer Beteiligungsgesellschaft der B. Braun Melsungen AG, fast ausschließlich vertrieben. 1972 wurde dann, nach dem Tod meines Vaters, die TRACOE GmbH, gegründet. TRACOE stellt als Wareneichen



Abb. 1: Vater und Sohn Köhler

und Firmenlogo eine sinnvolle Verbindung zwischen dem Produkt und dem Namen meines Vaters her.

**AM:** Wie erklären Sie sich den Erfolg einer handwerklich gefertigten Spezialität, an die im Interesse des Patienten höchste Ansprüche zu stellen sind?

**Dr. K.:** Die Fertigung in Handarbeit bietet uns die Möglichkeit, aus einem besonders flexiblen und schmiegsamen, glasklaren Material eine gewebefreundliche, für den Patienten angenehme Kanüle von hoher Qualität herzustellen und zwar in



Abb. 2: Links die extra lange Kanüle (nach Hautant). Daneben die Sprechventilkanüle.

allen Größen, vom Kleinstkind bis zum stattlichen erwachsenen Menschen. Darüber hinaus können wir in Ergänzung unserer kompletten Produktpalette auch Sonderanfertigungen anbieten, wie beispielsweise überlange Kanülen mit verschiedenen Sprechventilen oder mit Univer-

salaufsatz und Kanülen in jeder Sonderlänge. Wir können auch auf Wunsch sofort Sprechventilkanülen mehrerer Typen mit Fenster nach Maß anfertigen. Zusammenfassend gesagt: Wir bieten dem Arzt und damit dem Patienten mit *sofortiger* Lieferung immer eine genau passende Kanüle.

**AM:** Sie stellen Produkte von hoher Qualität für Märkte mit vielen Konkurrenzprodukten her. Macht Ihnen diese Konkurrenz zu schaffen?

**Dr. K.:** Ja, natürlich! Und man hat auch hier und da versucht, unsere Kanülen zu kopieren.

**AM:** Welche Vertriebswege haben Sie gewählt?

**Dr. K.:** Da uns im Interesse des Arztes und des Patienten an einem kompetenten Vertrieb gelegen ist, liefern wir *nur* über den Fachhandel. Diese Händlertreue hat sich bewährt. Das gilt auch für das europäische wie außereuropäische Ausland, wo wir renommierten Großhändlern ein exklusives Vertriebsrecht einräumen, denn wir sind zu der Überzeugung gelangt, daß nur ein ebenso kompetenter wie kontinuierlicher Vertrieb die pünktliche Versorgung des Patienten sicherstellt.

**AM:** Und wie sehen Sie die Zukunft für Ihre Produkte?

**Dr. K.:** Mit vorsichtigem Optimismus, denn drastisch steigende Rohmaterialpreise wie auch andere Kostensteigerungen werden uns zu schaffen machen. Aber wir gehen auch heute davon aus, daß sich unsere flexiblen Trachealkanülen weiterhin durchsetzen werden.

**AM:** Wir danken. ■

Sprechventilkanüle Typ A mit aufschiebbarem Silberventil

Standardkanüle mit Innenkanüle

## Flexible Kunststoff-Trachealkanülen

Standardkanüle ohne Innenkanüle  
Standardkanüle mit Innenkanüle  
Kanüle extra lang (nach Hautant)  
Kanüle mit Universalauflaufsatz für Narkosegeräte und Siebaufsatz  
Sprechventilkanüle Typ A (mit aufschiebbarem Ventil)  
Sprechventilkanüle Typ B (mit schwenkbarem Ventil)

**vollflexibel  
guter Sitz  
gewebefreundlich  
leicht im Tragen  
stumpfe Ränder  
durchsichtig  
unauffällig  
durchlässig für  
Röntgenstrahlen  
leicht zu reinigen**

in den Größen 4–14 mm Innendurchmesser (lichte Weite), gemessen am unteren Ende der Außenkanüle, erhältlich. Sonderanfertigungen möglich. Über den Fachhandel und Apotheken. Bitte fordern Sie unseren Katalog an.

**TRACOE**

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Telefon (0 60 39) 4 15 00

Wolfgang Köhler introduces TRACOE and his father's tubes in interviews in trade journals

### New international distribution channels

In the mid-1970s international business was also growing increasingly: through a pharmacy in Alsace contact was made with the French company Pouret Médical, to this very day the exclusive distribution partner of TRACOE medical in France. Further exclusive contracts with distributors in Switzerland and Denmark followed in 1975. And after the first major order came from France, suddenly more enquiries were also received from other countries. Now Köhler simultaneously negotiated with interested companies from the USA and the Netherlands and even initiated initial links with Australia, New Zealand, Taiwan and India. And so Köhler's tremendous commitment to domestic sales and the foreign partners soon made up for the loss resulting from the break with Pfau-Wanfried. In fact, B. Braun Melsungen, the parent company of Pfau-Wanfried, was now also placing larger orders with TRACOE again. But major progress was also made on the production side at that time, as Waldeck had continuously been developing the tracheostomy tubes. The success of the swivel speaking valve type B, which Waldeck had developed together with Gunther Nagel, a member of the production staff, and patented in 1974, was particularly phenomenal.

The crisis of 1973 had mobilised all Köhler's energy, and in a short space of time the crisis threatening the very existence of the company was averted. What was still missing, however, was a long-term corporate strategy. Despite rising sales and growing demand at home and abroad, the company still had no sound economic basis. At the time, the Waldeck and Köhler families mostly financed investment in tools and accessories from their own private assets. Waldeck was able to manage the important product development only alongside his demanding job at Boehringer. Wolfgang Köhler managed TRACOE to some degree in such a way that it could be wound up at any time: costs kept as low as possible, short-term cancellable contracts with freelance workers, the office in his own home, production in the private dwelling of Karl Beckhaus, with packaging, warehouse and dispatch in the private dwelling of Franz Waldeck. TRACOE remained an "on demand" company.

# AT FULL STRETCH ON THE ROAD TO SUCCESS

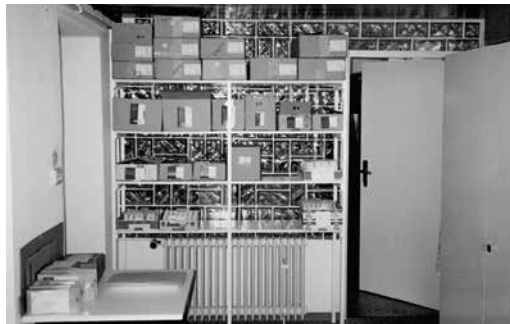
## Business picks up again

It was a major accomplishment, but, after a tremendous effort, the situation finally eased at the end of the 1970s. Focusing on high-quality and specialised products now gave TRACOE an edge over the competition's mass production for use in hospitals. In 1980 the young company rented two basement rooms in Mainz-Hechtsheim for production for the first time. Just as before, there the tubes were made by hand under the leadership of Karl Beckhaus. The speaking valves were made externally by Gunther Nagel, then glued onto the cannulas by Gisela Beckhaus. When an order was placed, the tubes were packed in a plastic box to which labels showing type and size designation had been affixed, and sent to the customer.

Meanwhile the TRACOE tubes, which were pleasant and comfortable to wear, had well and truly pushed the metal tubes out of the market. But the range needed to be expanded if they were to survive in the growing competition for plastic tubes. So from 1987 onwards, TRACOE also offered special sizes for children and in so doing opened up a further important market.

In this period, however, TRACOE's development slowed down, less due to competition but instead as a result of the rapidly increasing cost-containment policy in Germany's healthcare system. Since the 1970s the legislative authority had been attempting to further

Warehouse and production before certification



Bitter controversy regarding the healthcare reforms: demonstration in 1999.

reduce costs in the hospital and healthcare sector by numerous healthcare reforms. Domestic revenue took a sharp downturn in 1988, also largely for this reason. Unfortunately, however, sales abroad also fell sharply at that time. The French authorised distributor Pouret ordered around 24% less in the first half of 1988 than in the previous year – a result of the fierce competition that had meanwhile reached even the French market. Luckily, however, this downturn in revenue was quickly offset thanks to new product lines and skilful, strategic advertising and marketing measures. So in 1989, the year the Wall came down, TRACOE

recorded DM 1.8 million, the highest turnover in the company's history.

Wolfgang Köhler was convinced that TRACOE could continue its strong growth by means of even more targeted distribution, at national and international level. In the middle of this time of great opportunities, Wolfgang Köhler died quite unexpectedly in 1990. A huge shock for the family and the company. Luckily, however, in contrast to his father, he had meticulously appointed his successor and bequeathed his shares in TRACOE to his son. The vision: Stephan Köhler was to continue to run the company together with Professor Waldeck. A difficult legacy: Stephan Köhler, having so suddenly become an entrepreneur, faced difficult challenges and the transition to the third generation was a rocky road.

1990–2000

## ON COURSE FOR GROWTH

*A big responsibility at a young age. After the sudden death of his father, Stephan Köhler became a member of TRACOE senior management in 1990 at only 22 years of age. Together with Franz Waldeck, the young man made the company future-proof. Within a very short space of time not only were the firm's relocation and expansion of operations accomplished, but numerous innovations were also introduced. In particular, the new production facility in Mainz, the important CE-certification, and the consistent expansion of the product portfolio were milestones of that period. They had done it: in this period TRACOE finally made the leap to the next level and was suddenly dynamic, growth-oriented, and future-proof as never before.*

# INNOVATION AND MARKETING

### **Change of generation with turbulent signs**

Surprising, unprepared – for Stephan Köhler, who in 1990 was just 22 years of age, taking over the company after his father's sudden death came as something of a shock. His father had indeed made arrangements for handing over to his son but Stephan Köhler was still far from being an entrepreneur. He had neither completed his training to become a banker nor had the time to find his feet in his new role with so much responsibility, as he had to make some fundamental decisions – and make them now.



*The young managing director Stephan Köhler, 1997*

### New company address

One of the decisions that could not be put off any longer was, for example, the long overdue relocation of the company. Background: his father's private dwelling, which had been the TRACOE GmbH head office since 1972, had to be closed down, so new premises for the company headquarters urgently needed to be found. Luckily, in this precarious situation, the managing director of a marketing company whom he knew offered him two offices in his agency in Frankfurt's Reichsforststrasse. TRACOE moved in there that same year. During his training and subsequent business administration studies, Stephan Köhler enthusiastically familiarised himself with all aspects of marketing, distribution, balance sheets and also tax matters. His mother Karla Köhler and Wolfgang Ringel, TRACOE's tax consultant at the time, gave him valuable support during this period. Elisabeth Friedrich, a long-serving employee of the company, and his elder sister Catharina were also close at hand at this time.

In fact, Franz Waldeck had his doubts at first as to whether the young Stephan Köhler was of the right calibre for the enormous responsibility of a managing director. But ultimately he had faith in this dedicated young man; after all, they shared a common goal, to put TRACOE on a broader,



*Siblings Catharina Jurisch and Stephan Köhler*

*Head office of TRACOE GmbH in Reichsforststrasse, Frankfurt*



more sustainable footing with new products and a larger customer base. When Waldeck resigned from the Boehringer management board in 1993, he joined the company as managing director alongside Stephan Köhler and now finally had the time to dedicate himself intensively to product development. The success of this joint operation soon dispelled any remaining doubts about the qualification of the young Stephan Köhler, as Stephan passed his entrepreneurship test soon after starting.

The two largest German customers were alarmed by the change in the TRACOE management. The wholesalers did not want to lose their trusted supplier but probably hoped to be able to take over the company or at least to secure exclusive contracts. But Köhler stood firm, consistently rejecting any calls for exclusive contracts which would have meant the effective end of independence. However, this soon resulted in the two wholesalers marketing competing products. As luck would have it, at precisely this time one of the industry's most successful salespeople with his own sales office for medical equipment and devices became self-employed. He proposed to Köhler that he would also continue to market the TRACOE tubes, which not only offset the losses but

TRACOE also derived considerable benefit from the rapid and unexpectedly great success of this new partner.

The bottom line, however, was that time would show both Köhler and Waldeck that TRACOE was coming under increasing pressure from competition in its hitherto relatively safe niche. Furthermore, in the early 1990s, major healthcare reforms were announced in Germany, putting a further strain on the entire market. It was obvious that, faced with these enormous challenges, TRACOE GmbH could survive and secure the future only with a clear and future-oriented corporate strategy. But to do this, the company had to invest even more than before in marketing, national and international distribution, the development of new products and, above all, in developing modern, efficient production.



# INTERNATIONAL BRAND NAME

## On course for internationalisation with marketing

In 1990 TRACOE generated almost 70% of its turnover in Germany – achieved with relatively few major customers. In order to grow the business further and at the same time reduce dependency on large customers, Stephan Köhler had set himself the goal of acquiring as many new customers as possible. He was already looking beyond the national borders and saw enormous growth potential abroad. With an effective marketing strategy TRACOE was to develop into a strong brand – and at international level.

There had already been articles on TRACOE products in professional journals in Wolfgang Köhler's time, likewise product descriptions, standardised packaging, and even a catalogue – but at that time it was all still available in a very simple form. The tubes were supplied in plain plastic packaging, frequently with a wholesaler's sticker, so customers and patients were often unaware that they were using a quality product from TRACOE. This was to change. The marketing agency where TRACOE had been set up was now called upon to develop a modern, attractive corporate design with a high recognition value. This had an impact, particularly in the case of the packaging. The simple plastic boxes were replaced with very attractive cardboard packaging in the new corporate design. So many patients who had already been using the product for years now became familiar with the company for the first time. But that was not all: with targeted advertisements and specialist articles in the trade press, TRACOE became better

*TRACOE becomes a brand name:  
first company logo of 1988*

# TRACOE®

*Packaging for the TRACOE comfort in 1994*



*Regularly represented at trade fairs since 1990:  
(Left.) Elisabeth Friedrich and Stephan Köhler*

known among the decision-makers – doctors and clinical personnel – and accurately positioned.

The new marketing strategy also included presence at national and international trade fairs. Starting in 1994, Catharina Jurisch, Stephan Köhler's sister, organised the first trade fair presentations for example at Interhospital in Hanover and the Medica in Düsseldorf. The stands were small and the only company representatives were Elisabeth Friedrich and Stephan Köhler. The exhibition stands increased in size and became more professional in line with their growing success. Trade fairs and events abroad soon followed, making TRACOE increasingly well-known. Through direct contact with the customers and patients, the company strengthened its competitive position – and in addition received suggestions for improvements and new products.

*Stand at MEDICA 2002*





Receiving various national and international certifications was of crucial importance for the company

### The internationalisation strategy pays off

Dr. Wolfgang Köhler had already acquired his first foreign customers in 1972. But now the time was right and opportunity was knocking for Stephan Köhler; he wanted to develop these contacts and extend distribution to further countries. Whole new markets opened up for TRACOE, particularly in the former Eastern bloc. TRACOE soon gained a foothold in other countries too, winning new partners in western Europe, Asia, and America. By 2002 foreign sales rose to 70% of total revenue – although domestic sales also showed a constant rise. Köhler's concept was an unqualified success: TRACOE had established itself in the German market within a few years, at the same time gaining significantly in terms of stability and security due to the enormous success in exports.

Good products and reliable production in particular were prerequisites for the huge successes in sales. At that time – the early 1990s – CE-certification under the European Single Market Directive brought pressure for change. All companies wanting to sell products inside the European Economic Area had to be certified by 1998. At TRACOE the tubes had hitherto been made using outworkers, while finishing, storage and dispatch still took place in rented basement rooms. Certification under these conditions

was inconceivable.

So TRACOE prepared everything to change the situation. By 1994 the company had acquired new premises in Mainz-Hechtsheim for production, warehouse and dispatch and immediately applied for the coveted CE-certification. The company now finally had a production facility that met modern international standards – albeit still without a cleanroom. In 1994, TRACOE was one of the first companies in the industry to be given QM certification to DIN EN ISO 9001 in conjunction with EN ISO 46001. Important North American and Japanese certification was subsequently added. Without this seal, TRACOE would not have been allowed to sell any products in the EU after 1998 at the latest. The course was therefore set for further growth and export.

## TRACOE *twist* – multifaceted

Officially launched in 1996 and immediately making its mark: TRACOE *twist* is a true milestone in the company's history, as this was the product that enabled TRACOE to make the breakthrough into the hospital sector. Patients and nursing staff alike benefit from TRACOE *twist*.

The main advantage lies in the wide range of use. TRACOE *twist* tubes are used as ventilation and therapy tubes in hospitals, rehabilitation clinics and community care. The anatomically shaped neck flange, which moves in both the vertical and horizontal planes, offers patients more freedom of movement, while the inner cannula system makes it possible to clean the inner cannula without having to remove the entire tube. Further developments led to the *twist plus*, which adds a longer and even thinner tube with inner cannula system to the portfolio. It is characterised by an extremely good ratio between the outer diameter and the inner diameter. Both products are available with different features, such as a cuff for controlled mechanical ventilation, subglottic suction for the management of secretions or fenestration to allow air into the upper respiratory tract.



# NEW DIMENSIONS

## Product development increasingly successful

Actually TRACOE still offered only one product at the beginning of the 1990s – in different versions, but nonetheless only one product. Yet Stephan Köhler and Franz Waldeck were 100% certain that without further products – more “blockbusters” – the company would not be able to hold its own for much longer. Fortunately Franz Waldeck had had this bright idea in mind for a long time: from 1993 onwards TRACOE developed an innovative product so as to have a presence with a strong quality product not only in the HomeCare sector, but also in the hospital sector. The development took almost three years and was by far the biggest investment in the company’s history. It is only honest to admit that the decision was also a very risky one, as failure would have brought TRACOE literally to the verge of ruin.



Franz Waldeck and Stephan Köhler ca. 1990

**WHY TRACOE PAYS SO MUCH ATTENTION TO DETAIL.**

There are many little reasons for the big success of the new TRACOE *twist* line of tracheostomy tube products. Take, for instance, the anatomically shaped optimized neckplate that rotates in two axes so patients can turn their heads freely without exerting excessive pressure on the trachea. Or the thin-walled, thermoflexible polyurethane tubes, which are very light and soft and provide a wider air channel that makes it easier to breathe. Or the very soft, low-pressure cuff with a balloon you can finely adjust to ensure an optimum tracheal seal at all times. Or the fact that every tube comes with an inner cannula.

You also benefit from the modular design of our products, because all types of inner cannulas are separately available. This generates major savings. For more information, ask for our full-line catalog today.

**TRACOE®**  
*twist*

TRACOE medical GmbH, Reichsforststr. 32, D - 60528 Frankfurt/Main  
Tel. +49-69-665 668-0, Fax -10, E-mail: info@tracoe.com

International advertisement for TRACOE *twist* with the new TRACOE logo developed in 1999

## A milestone in TRACOE history

But the expense had paid off. In 1996 the time had finally come: TRACOE presented a milestone in the history of the company with the TRACOE *twist*. This tube finally achieved the breakthrough into the attractive hospital market. TRACOE *twist*, the new product highlight, was introduced from the outset as a complete product family as its scope of application was very varied. It was used for mechanical ventilation under anaesthesia, for long-term ventilation in the intensive care unit, and also for the subsequent care of patients. The tubes were made of radiopaque, tissue-friendly polyurethane without any plasticisers. The walls were particularly thin, to guarantee maximum airflow. Though having the same outer diameter, its inner diameter was significantly larger than any of its competitors. Also, thanks to the anatomically-shaped flange that could swivel round two axes, patients were also able to move their necks freely without exerting more pressure on the trachea.

The standard product was also given a new name to make it easier to distinguish between the old and new tubes. From then on, the tubes developed by Rudolf Köhler in 1958 were called TRACOE *comfort*.

**TWIST & COMFORT:  
IDEALLY COMPLEMENTING EACH OTHER.**

The product line TRACOE<sup>flex</sup>, newly introduced by TRACOE in 1996, will now be sold under its new name **TRACOE<sup>twist</sup>**. The advantages of this high quality tracheostomy tube, however, are the same: made of smooth, white polyurethane, they are radiopaque, sterile, very light and flexible! The anatomically shaped swivel neckplate moves around two axes. The favourable relationship of quality to price makes them particularly attractive for use in hospitals.

TRACOE's other product line, **TRACOE<sup>comfort</sup>** are tracheostomy tubes made of transparent, flexible PVC which have been permanently further developed and successfully sold for more than 30 years now. **TRACOE<sup>comfort</sup>** tubes guarantee a maximum of comfort and cosmetic appearance to the long-time wearer.

TRACOE<sup>twist</sup> **TRACOE<sup>comfort</sup>**

hospital permanent use

Surgery, Intensive Care post-operative phase after tracheostomy

TRACOE<sup>twist</sup> and TRACOE<sup>comfort</sup>: two product groups which ideally complement each other.

**TRACOE**<sup>®</sup>

TRACOE GmbH, Martin-Behaim-Str. 12, D-63263 Neu-Isenburg  
Tel. +49/61 02/77 69 90, Fax +49/61 02/77 69 99

**NEW!**  
TRACOE GOES WWW:  
<http://www.tracoe.com>

Please ask for our new catalogues!

Advertisement from 1998: TRACOE twist and TRACOE comfort

# THE PATH TO BECOMING A FULL-SERVICE PROVIDER

## Setting new goals

The change was complete – within a few years Stephan Köhler and Franz Waldeck had developed a future-proof, multinational company from a micro-enterprise with outworkers. The key to their success was professional marketing, making TRACOE both well-known and sought-after in equal measure among customers and patients. New distribution partners at home and abroad and new products increased sales, and entering the highly competitive hospital market had also succeeded. Yet the entrepreneurs neither wanted nor were able to rest, as competition in the increasingly globalised market was becoming more and more intense – and harder. Real low-cost providers pushed their way into the hospitals, particularly abroad where cost pressure called for savings even more so than in Germany. TRACOE not infrequently lost out on invitations to tender, as the company was unable to offer cheap tubes.

The success of TRACOE *twist* immediately exceeded all expectations and also reassured skeptics, of which there were a considerable number at the time. They had feared that the tried and tested TRACOE *comfort* would be cannibalised by the new product. A gross error of judgement as, in fact, precisely the opposite happened: in hospital many patients became familiar with TRACOE tubes and also trusted the Frankfurt company's products later at home.

The new tubes gave the company an enormous growth spurt, in the sales of both TRACOE *twist* and the traditional TRACOE *comfort*. Between 1995 and 1998 turnover climbed from DM 3 to 4.6 million. In this period, the company hired 22 new employees and support staff in order to cope with the growth in demand. Since 1990 personnel numbers had risen from just 6 to 47 employees.

**WIE TRACOE  
AB SOFORT AUF  
DRUCK REAGIERT.**

Eine lebenswichtige Aufgabe aus der Intensiv-Medizin lautet: Wie kann bei der künstlichen Beatmung eine kontinuierliche und exakte Überwachung des Cuff-Druckes von Tracheostomie-Kanülen und Narikostubien sichergestellt werden? Die Lösung ist **cuff pressure control**. Das neue, äußerst kompakte, mobile und leicht bedienbare Präzisionsgerät von TRACOE erfasst automatisch alle Druckänderungen und kompensiert sie sofort.

**cuff pressure control** bietet mehr Sicherheit für den Patienten, schützt vor Pneumonien und hilft Drucknekrosen zu vermeiden. Die Folge: Die Liegezeit ist kürzer, Anästhesisten und Pflegepersonal werden entlastet.

Katalog anfordern!

Besuchen Sie uns auf der MEDICAL Halle 5 Stand 5 K05

**TRACOE**<sup>®</sup>

TRACOE GmbH, Martin-Behaim-Str. 12, D-63263 Neu-Isenburg  
Tel. 06102/7769-00, Fax -69, <http://www.tracoe.com>, E-Mail [info@tracoe.com](mailto:info@tracoe.com)

TRACOE cuff pressure control: advertisement from 1998

### Growing challenges

At that time, the winds of change blew stronger in the German home market. Despite innumerable reforms, costs in the healthcare system continued to rise. Budgets were intended to reduce costs in hospitals, reduce length of stay, and treat as many patients as possible as outpatients. Numerous hospitals found themselves facing financial difficulties as a result. In this situation, large corporate groups evidently had a better starting position than small and medium-sized enterprises like TRACOE, as they could offer their products more cheaply and through their own sales force.

TRACOE faced difficult times. For example, hospitals began to reduce the number of suppliers – a trend that persists to this day. It was obvious: with TRACOE *twist* and TRACOE *comfort* alone, the company would not be able to hold its own in this highly competitive market in the long term. But what needed to be done? Did TRACOE have to become a full-service provider in its field? Yes. But in 1998 the company still had a long way to go. TRACOE needed to systematically develop more products that either helped the patients to cope better with their disease or improved the work processes in the hospital. At that time there were already parallel plans and prepara-

tions made for entering the laryngectomy sector.

### Expanding the product portfolio

In 1998, TRACOE started with cuff pressure control, the second big new development within just two years. The new product was to increase the safety of patients and simultaneously make life easier for medical personnel in hospital. Background: the air pressure in the cuff (the balloon on the end of the tube which seals the trachea) was usually adjusted manually using a handheld manometer and was checked at regular intervals. Errors could cause significant complications. The secret: with cuff pressure control, the air pressure in the cuff was regulated automatically for the first time. And although sales of the TRACOE cuff pressure control (cpc) failed to meet expectations initially, Stephan Köhler and Franz Waldeck stood by the product. They were firmly convinced that hospitals would soon realise that this highly innovative product would markedly lighten the load for their personnel.

TRACOE cuff pressure control in 2006



## TRACOE *technic* – safe cuff pressure

It was the TRACOE innovation of 1998: cuff pressure control. The electrical device for regulating cuff pressure brought the tracheostomy tube into the technological age.

Cuff pressure control allows the air pressure in the cuff to be set correctly for the patient and monitored at regular intervals. It is important that the cuff is always correctly inflated, so that the patient can be sufficiently ventilated at all times. The risk of silent aspiration and tracheal injury are thereby reduced.

From this beginning, a complete programme for precise cuff pressure management has been developed, with a major new TRACOE innovation coming on to the market in 2013: the TRACOE smart Cuff Manager regulates cuff pressures without any electrical source. It maintains the internal pressure of the cuff at between 20 cmH<sub>2</sub>O and 30 cmH<sub>2</sub>O. It is easy to use and the visual confirmation of the optimal cuff pressure reduces the load on nursing staff, both in hospitals and in the HomeCare setting.



In 1998 TRACOE launched two more innovations on the market, the stoma button and the grid button. Both buttons were made with those patients in mind who no longer needed tubes but whose tracheostomas nevertheless had to be kept open. They could also be used as aids for voice rehabilitation. These were followed three years later by various speaking valves and heat/moisture exchangers (HMEs) which further improved patient comfort.

TRACOE stoma and grid button, 1998



TRACOE heat/moisture exchangers (HME) and speaking valve, 2001



## TRACOE *modular* – for the patient's wellbeing

Starting in 1998, TRACOE rounded off their portfolio with a range of stoma buttons, short cannulas, speaking valves and heat/moisture exchangers (HMEs). The products were systematically designed to be compatible and can be combined according to need and indication. The TRACOE phon assist I speaking valve is used for tracheostomised patients and, thanks to its infinitely adjustable airway resistance, offers new therapeutic options such as weaning from ventilation, improving oropharyngeal perception and for voice projection in children. The TRACOE phon assist II speaking valve offers the possibility of hands-free speech to laryngectomised patients with a voice prosthesis and to tracheostomised patients. Both valves can be individually adjusted to the patient. The heat/moisture exchangers act like an artificial nose to filter, warm and moisten the inhaled air.

The TRACOE *modular* range is continuously being improved and extended – thus making an important contribution to a better quality of life for the patient.

### The first sales manager

A further milestone in the company's development was the appointment of a manager for international sales, as the growing product portfolio and increasing turnover also required further improvements in the sales area – in particular abroad. Until then, Stephan Köhler had largely been organising things alone and had opened up numerous markets abroad himself. But this could not be sustained in the long run, also because more and more dealers had to be trained for the new products and more and more dealers had to be attracted.

In 1998 TRACOE took the plunge with Bernhard Schneider and, in him, appointed a proven sales expert as manager for foreign sales. Schneider, who had previously been responsible for the sales department at Leica laboratory equipment, was immediately enthusiastic about TRACOE's products and development. He consistently built up foreign sales and, among other things, compiled an extensive sales guide for the dealers with detailed information on all the products and specific assistance for selling them – a tool that would become an invaluable advantage for all the retailers. And a new sample case containing all TRACOE's products provided the perfect means of presentation.

Further important measures: Bernhard Schneider quickly introduced financial control in sales, extracted sales figures, created budgets and detailed forecasts, and talked to numerous retailers about their experiences with the distribution of TRACOE products. He was firmly convinced that a small, specialised company like TRACOE needed to have all the more presence among retailers. At the same time, the intensive exchange of experiences also indicated the needs of customers and the market. Through seminars and workshops, TRACOE showcased the core competencies of the company: outstanding products, professional expertise, and fast delivery. New effective contacts with retailers the world over were established equally quickly at trade fairs and conferences.

### Big visions, big plans

It was the beginning of a new era: new products and more and more employees – the company was constantly changing and growing rapidly. But one thing was clear: the leap into the 21<sup>st</sup> century was not possible with production in its current state. Franz Waldeck therefore acquired a property together with administration and production premises in Nieder-Olm near Mainz that was ideal for the company's requirements. Then in 1999 he built a production facility on around 1800 square

metres with cleanrooms, a large warehouse and a development department, which equipped the company perfectly for the future. Production started with 39 employees in the middle of 1999. And while many products were still being made by hand, some manufacturing steps could be automated. TRACOE tailored the required technology together with an engineer.

The company continued to develop in other areas too. A year later – in 2000 – Stephan Köhler acquired the building where TRACOE had its first office, and after an intermezzo of just three years in Neu-Isenburg, the administration returned to Reichsforststrasse, Frankfurt am Main. They were ready for the new millennium: TRACOE was not only healthy and ideally positioned for the future but also had many new plans for the coming years.

*Case containing the products TRACOE twist and TRACOE comfort, 2004*



*“The right man at the right time: together, Schneider and I laid the foundation – our successful international business”*

Stephan Köhler

2000–2013

## CONSOLIDATION AND EXPANSION

*TRACOE did not always have it easy in the subsequent years: in Germany, costs in the healthcare system were rising, the market for medical devices was highly competitive. At the international level, competitive pressure from low-cost providers was increasing. Yet against all the odds, TRACOE remained true to its chosen path, stood by its idea, and responded to the challenges in the market with new products and the building up of its own sales force. A new production facility and a new head office offered opportunities for growth, so that after the turn of the millennium TRACOE would succeed in establishing itself as one of the most innovative companies in the industry and lead the medical market in the field of tracheostomy and laryngectomy from then on.*

## DIFFICULT MARKETS

### **Innovation and the principle of maintaining the highest level of quality**

With new and more refined products and active foreign sales, TRACOE medical GmbH, as the company was called after 9 February 2001, was well prepared for the future. This was also imperative, as market pressure was continually increasing with the concentration on the customer side and low-cost providers emerging. TRACOE responded and chose the way forward: with innovative products and the self-defined guideline of providing the best quality in order to make life easier for patients and make the work of doctors and nurses easier.

In the years that followed, the company launched numerous new products onto the market. In 2002 TRACOE added tracheal compresses, neck straps, and a variety of care products to the care product group. The medical technology manufacturer further expanded the *larynx* product group, which was specially developed for patients who had had laryngeal surgery, adding a variety of voice prostheses. And the development of tubes also progressed quickly. In 2002 the company introduced the TRACOE *vario*, a flexible tube without an inner cannula for use in hospitals. The company even had one component of the product patented: with a variable adjustable flange, the *vario* tube could easily be adjusted for each patient individually – a special feature. A year later there was a new milestone with the launch of the TRACOE *mini* tube: the company added products to its portfolio which

*The sterile packaging of the tubes conforms to the most demanding hygiene regulations*





met the special, very specific needs of children and neonates, as the tubes were particularly soft with thin walls, but nonetheless dimensionally stable.

#### Distance brings sales to a halt

However, things did not seem to be running smoothly somewhere, as sales of the products at first did not go as TRACOE expected. But the problem area was soon identified: customers needed explanation as regards the niche medical devices. The crux of the matter was the sales structure. In the HomeCare sector TRACOE had fostered long-standing, well-established partnerships with pharmacies and specialist healthcare retailers. But many hospitals where the TRACOE tubes were used for patients were in the midst of upheaval and simultaneously under considerable cost pressure. Product suppliers like TRACOE therefore did not deal directly with the senior physicians or nursing managers but with the external purchasing departments of the growing number of private hospital chains, large buying groups or even those of individual hospitals – the distance from the user was therefore simply too great.

As TRACOE had previously worked with exclusive distribution partners in the hospital sector, consequently there was no

direct contact with the hospitals nor any discourse about the products with the users. This became abundantly clear in the case of the TRACOE *vario*, the tube specially designed for hospital needs, which at first failed to reach the desired sales figures.

But how could TRACOE develop proximity to its customers to explain its products? The solution: the company established its own sales force who would make contact with the hospitals, explain the products to the buyers and decision-makers, and provide the medical staff with qualified advice on the products. Implementation followed soon afterwards. In 2004 TRACOE built up its own sales department under the direction of Willy Weyland. At that time he had had over 30 years' experience with reputable companies in the medical technology industry, including as executive officer in the surgical and HomeCare segments at Kendall (now Tyco). The task of building up the sales force in a small firm with all its particular challenges appealed to Weyland. Four sales personnel for different sales regions within Germany and a specialist in product training would from now on explain and sell the TRACOE tubes in hospitals.



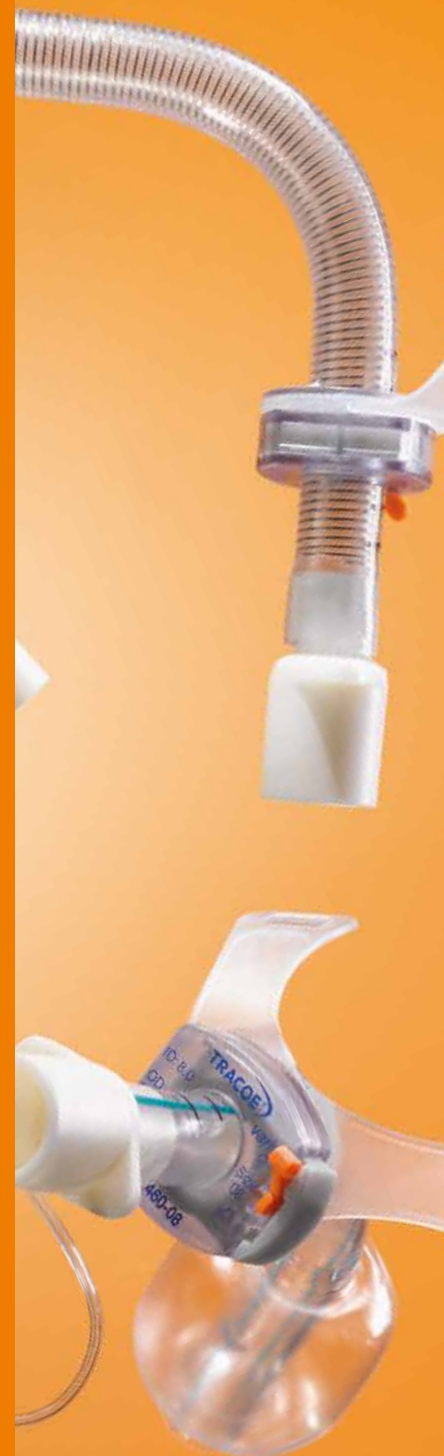
*From left to right:  
Willy Weyland,  
Bernhard Schneider,  
Martin Weyland,  
Gerlinde Müller-Daniel*

But the sales team for Germany was only the beginning, as Köhler could see potential especially abroad. "The sales staff must be appropriately trained so that our products are used correctly and their quality is evident. However, international retailers sell many other products in addition to ours, and are not trained specialists for our tubes. Our local distribution partners therefore repeatedly require intensive advice and training". Here Köhler saw one of the key tasks for TRACOE in the coming years: to work more closely with retailers worldwide, increase their product knowledge, and thereby improve the service.

## TRACOE *vario* – patented precision adjustment

In 2002, TRACOE presented a tube that, thanks to its patented neck flange, can be individually adjusted to each patient – a significant improvement for doctors and nurses working in hospitals.

The TRACOE *vario* system has been meticulously thought out down to the last detail. By means of a practical push-button mechanism, the neck flange can be adjusted to the individual patient. The two flexible wings on the flange can also be adjusted independently of one another. A printed scale ensures the exact positioning of the neck flange, even after a tube change. The right solution for each patient can be selected from the eight types of TRACOE *vario* tracheostomy tubes available. For example, there are tubes that are reinforced with a metal spiral, tubes made of transparent plastic (with radio-opaque contrast lines), fenestrated tubes and tubes with or without a cuff. Additional tubes with special features are the extra-long TRACOE *vario* XL with metal spiral and TRACOE *vario* extract in clear plastic and equipped with a subglottic suction line – both with cuffs and, of course, also available in standard lengths.



TRACOE *vario* tubes from 2004

### Special department for research & development

The desire for customer proximity and reliable cooperation with the retailers throughout the world was not to be aimed only at successful sales. In this way, the TRACOE sales team was also able to learn about conditions that were often very different from country to country, gather valuable knowledge about the needs of physicians, nursing staff and patients locally, and take the information home with them. A distinct advantage – especially for the development of new products.

True to the motto “Quality by People for People”, from the outset it has been TRACOE medical’s intention to improve the quality of life for patients and the treatment success of physicians in the long term and to develop relevant products that meet the individual needs of patients to the highest standards. Köhler realised that the high quality requirements could only be guaranteed if, in addition to sales, TRACOE set up its own research and development department and retained responsibility for production from A to Z in their own hands. No sooner said than done: in 2004 TRACOE set up this unit and entrusted Dr. Ralf Schnell with its management. Since then, the research & development department has been responsible for developing ideas for new products, constantly improving the manufacturing process, and refining the existing portfolio, all the while taking current research into consideration and through cooperation with hospitals. For that reason, among others, TRACOE medical is an international pioneer in medical technology in the field of tracheostomy today.

### The portfolio grows – with TRACOE *pure* and TRACOE *experc*

Two years later, in 2006, the company introduced TRACOE *pure* and TRACOE *experc*, two important product innovations for the hospital sector. TRACOE *pure*, a tube with no inner cannula and no adjustable flange, was designed for short-term use with patients and, due to its low price, covered an important market segment. This made it easier for TRACOE to participate in invitations to tender in Germany and abroad, where a low price for the tube is essential.

Even more important, however, was the introduction of the TRACOE *experc* Dilation Set, with which the company responded to the trend in medicine towards percutaneous tracheostomy. With the percutaneous dilational tracheostomy (PDT) technique developed by the Italian Pasquale Ciaglia, the trachea was no longer opened by means of incision, but instead it was punctured. The tube was then introduced directly into the trachea following blunt dissection. Tracheostomy therefore no longer needed to be performed by an ENT specialist but could also be performed by anaesthetists or intensive care physicians. A further advantage of PDT: the tracheostoma healed quickly with this technique, and there was hardly any

scarring of the patient's neck.

TRACOE was critical of percutaneous tracheostomy at first. The company initially wanted to observe the development of PDT, as they did not consider the technique to be fully developed. However, in 2005, when the procedure had stood the test in scientific studies, was gradually becoming established in practice, and it became evident that the future lay in percutaneous tracheostomy, Dr. Ralf Schnell and his team quickly started to develop a product that met TRACOE's own quality standards. The set was to bring about distinct improvements for doctors and patients. For example, the minimally traumatic inserter to a large degree prevented injury to the trachea when the tube was inserted. It soon became clear: the product was a top seller. Similarly to the TRACOE *twist* just under ten years earlier, the TRACOE *experc* Set became a milestone for the company.

Advertisement for the TRACOE *experc* Set, 2007



## TRACOE *percutan* – innovation for the future

The TRACOE *experc* set for percutaneous tracheostomy, which was introduced in 2006, established TRACOE on the market as a problem solver for state-of-the-art tracheostomy procedures.

TRACOE spotted a crucial drawback in the percutaneous sets that were commercially available at that time – namely the change in diameter between inserter and tube, a difference that often led to injury. The TRACOE *experc* set offers the solution to this problem: a soft silicone sleeve at the tip of the inserter that bridges the gap and allows a minimally traumatic insertion. When the inserter is removed, the sleeve folds down and the inserter can be withdrawn safely and easily. International patents have been granted for this innovation, which was developed by Dr. Ralf Schnell.

There are 14 different TRACOE tracheostomy tubes with minimally traumatic insertion systems in the product ranges TRACOE *twist*, including *twist plus*, and TRACOE *vario*.





*The expirc Set is one of TRACOE's best selling products*

The set consisted of instruments to make a tracheostoma (Dilation Set) and a TRACOE *twist* tube with a special inserter which prevented trauma during insertion into the patient's trachea. It was accepted immediately by hospital physicians as an appropriate and practical tool. The TRACOE *percutan* product family to which the TRACOE *expirc* Set was assigned, had meanwhile been extended by the addition of sets with *vario* and *twist plus* tubes.

#### **The market demands, TRACOE supplies**

TRACOE always kept its eyes and ears open for sensitive market trends and

responded as ever to the needs of the doctors, nursing staff, and patients with the development of new products. For instance: as the conventional sizes of tube were not long enough for many overweight patients, TRACOE developed extra-long products and continues to expand the programme to this day.

In 2010, however, TRACOE launched a short tube made of soft, flexible silicone for patients on the road to recovery who no longer needed a conventional tracheostomy tube but only a device to keep the trachea open. The tubes could be

used for attaching speaking valves and/or heat/moisture exchangers (HMEs). The TRACOE *button plus*, a medical device launched in the same year, was used for the treatment of tracheostomised patients after long-term ventilation. The product secured the airway following removal of a tracheostomy tube and allowed the viscous mucus to be expectorated quickly.

In 2011 TRACOE added an enhanced version of the tried and tested *twist* tube with the *twist plus* series. The tubes were somewhat longer and helped the patient to breathe due to the even thinner walls. This meant a considerable improvement for the doctors in the hospital and the patients themselves. Liaising closely with suppliers, TRACOE therefore tried new techniques and materials at great expense to improve the *twist* tubes in the desired form.

#### **Pressure from outside: reforms call for change**

Developments in the market for medical devices and continual changes in the healthcare system time and again demanded TRACOE and other medical technology manufacturers to adapt. Mostly this meant that the cost pressure on the manufacturers increased at the same time, as also happened in 2007: when the new healthcare reform entered into force

it was no longer the physicians but the health insurers who decided from which supplier a patient obtained their tube for the HomeCare sector. This far-reaching change posed great challenges since the distance between the health insurer and the patient meant it was necessary for the TRACOE products to be explained and offered accordingly. Nevertheless Köhler emphasised: "We want to continue to grow in the HomeCare sector, just as in all the sectors where we offer products". Cost pressure remained high especially in the hospital sector. The hospitals therefore wanted to reduce the number of suppliers and concentrate on companies which were able to supply all the products in their field. TRACOE therefore realised: the company had to become a full-service provider of medical devices for tracheostomy and laryngectomy.

*"We want to continue to grow in the HomeCare sector, just as in all the sectors where we offer products".*

Stephan Köhler

# NEW PRODUCTION FACILITY

*Automated small parts and finished products warehouse, 2009*



## More space to produce tubes

With a constantly growing product portfolio and successful distribution, the company as a whole grew ever bigger. The capacity of the production facility acquired in Nieder-Olm in 1999 was therefore soon fully utilised. If they were to survive in terms of production costs and ability to deliver, also by comparison with international competition, the workflows in production also had to be optimised. So TRACOE decided to set up a completely new, bigger production facility, not even ten years after opening in Nieder-Olm. This expansion had become imperative, as turnover rose by 7% in 2008, and TRACOE also expected strong growth for the current year.

## Construction work starts and digitalisation moves in

Construction work commenced in Nieder-Olm in autumn 2008. A new production facility spanning around 3000 m<sup>2</sup> was built here at a cost of more than EUR five million. Following completion in 2009, TRACOE set up a cleanroom production unit, a fully automated small parts warehouse with picking stations, and a high-bay storage facility with a dispatch department. Production capacity quadrupled and manufacturing operations and logistics were considerably improved.

Great expectations were attached to the opening of the new production facility as many work steps were to be automated immediately and the workflow improved generally. The small



*Cleanroom, 2009*

parts warehouse, for example, was now accessed via a fully automatic computerised robot. Although hitherto parts of production always had to be taken to the other end of the building manually for further processing, now the workstations were arranged in optimum sequence and could be supplied with the required parts for the next manufacturing process almost completely automatically. Assembly was to take place predominantly in the cleanrooms so as to ensure the highest quality standards.

The traditional manual work remained indispensable, however, as only by this means could TRACOE medical implement its guiding principle of providing the best product quality and produce individual product variants of the tubes. At this point, many former and current employees were still familiar with the tubes being made by

freelance outworkers – this could hardly be compared with the modern production in Nieder-Olm any more.

In fact, the new production facility symbolised a significant change for TRACOE. Köhler summed it up: “Up to now we always had to adapt to the building, now the building is adapted to us”. Further changes were also on the horizon: “In future everything will be IT-based. It will certainly be some time before everyone has adapted to this, but we have confidence in our employees and know that the conversion will not pose a problem for them”.

—  
*“Up to now we always had to adapt to the building, now the building is adapted to us”.*  
 —

Stephan Köhler

In the years that followed, TRACOE medical continually increased production in Nieder-Olm. This also meant new plans for the future of the company. As Professor Waldeck was now 73 years old, both executive officers agreed to relocate the marketing, sales, and financial accounting departments, hitherto located in Frankfurt, to Nieder-Olm. They had been preparing for Waldeck's departure from the management board for a period of three years. The merging of the Frankfurt and Nieder-Olm sites was to improve communication between the facilities and the responsiveness and flexibility of production, and to intensify cooperation of the development department with sales.

The construction work for the administrative building with spacious offices and a total area of around 1200 m<sup>2</sup> commenced at the beginning of April 2012 and was completed by the following winter. The previous office and warehouse building was modernised at the same time and given new workrooms. As well as offices, the reception area and various conference rooms were also housed in the newly constructed connecting building. TRACOE invested several million euro in the overall reconstruction.



Stephan Köhler had already acquired temporary offices in Nieder-Olm before the planned relocation so as to be able to be on site during the construction phase. The big day came at the beginning of 2013: the Frankfurt staff could move to Nieder-Olm, but the official and complete relocation was set for 1 February 2013 and the following weekend – again a significant milestone for TRACOE.

#### **Painful loss of an eminent figure**

The move in fact marked the end and the beginning of an era in a quite different way, however. Professor Waldeck, who had had an exceptional impact on TRACOE with his knowledge and his personality, had become seriously ill in late summer the previous year. He died on Friday, February 1<sup>st</sup> – the very day of the relocation. His death clouded the company's expansion, which would otherwise have been a wonderful event, as in Professor Waldeck TRACOE had lost a key figure and pillar of the company. After the premature death of the founder Rudolf Köhler, Franz Waldeck had supported his successor Dr. Wolfgang Köhler with his knowledge and his experience through the first change of generation and later further expanded the business together with the latter's son, Stephan Köhler.

*Model of the head office building in Nieder-Olm*



Stephan Köhler and  
Franz Waldeck, 2009

Waldeck's contribution up to his death meant that TRACOE tubes were used in more than 80 countries worldwide.

#### Tasks for the future

With targeted marketing, professional sales and numerous new products, Stephan Köhler and his colleagues had turned TRACOE into one of the world's leading suppliers in the field of tracheostomy and laryngectomy. In 2007 the catalogue already listed some 3000 products in every available size and variant. TRACOE sold its products by means of exclusive contracts all over the world; in Germany a

dedicated sales force ensured a fast-growing business. The number of employees continually increased despite all the rationalisations.

TRACOE continued to focus on Germany as a location. In fact, although individual components were sourced internationally, production of the tubes remained in Germany. The company also wanted to make an impression on the international scene with quality products "Made in Germany"; Köhler und Waldeck were agreed on this before Waldeck died. On the 50<sup>th</sup> anniversary of the first PVC

cannula in 2008, Professor Waldeck once more affirmed his and Köhler's thoughts: "The personnel costs here are high but our employees are also highly qualified and productive. So in future we will continue to produce in Germany in order to fulfill our high quality requirements".

However the high personnel costs demanded production that was as efficient as possible – and without affecting quality. Köhler knew that only in this way would TRACOE be able to survive on the market in the long term.

After the death of Professor Waldeck, Stephan Köhler took control of the firm as sole shareholder. He used the transition to review company structures and undertake modernisations here and there if necessary. Köhler had no intention of resting on his laurels with TRACOE's enormous growth, as he was convinced that the challenges in the market would come at ever shorter intervals and simultaneously become significantly bigger. Köhler: "In the past, a strategy could be developed that would last for ten years or more. Today, that is no longer the case".

Köhler wanted to utilise the positive business performance to optimise the manufacturing process once again and

make it especially efficient. The company therefore invested heavily in the production process. The objective: TRACOE would become a full-service provider for medical devices in the field of tracheostomy and laryngectomy – with products that improve patients' comfort and positively affect healing, reduce the length of stay in hospital, optimise the workflows of doctors and nurses, and so even benefit the hospitals' budget in the long term.

Improve efficiency, drive innovations forward, boost sales at home and abroad, develop marketing, simultaneously bring production and administration staff together and establish common goals. Stephan Köhler had set himself ambitious goals. The executive officer was convinced that only in this way would TRACOE medical successfully engage the future.

*"In the past,  
a strategy could  
be developed that  
would last for ten  
years or more.  
Today, that is no  
longer the case."*

Stephan Köhler

2013–2018

## FIT FOR THE FUTURE

*After the death of Professor Franz Waldeck, Stephan Köhler became sole proprietor and managing director of TRACOE. However, given the constantly growing turnover, it soon became evident that, even on the new site, the company would reach the limits of its capacity. It was a huge task; action was needed in all areas. For this reason Köhler had had the support of Dr. Thomas Jurisch as second managing director since 2015. TRACOE subjected all the internal processes to an audit and restructured virtually every area. An international group was formed as a result of the take-over of the Dutch MC Europe (in 2011) and the interest in the British KAPITEX (2015/16). Together with business-minded unit heads, Köhler and Jurisch set the course for growth and earning power.*

# FACILITATING NEW GROWTH

### Optimisation in all areas

When Professor Waldeck died in 2013, TRACOE had already been growing at an annual rate of more than 10% for some years – but the company had clearly reached its limits. Köhler and Waldeck had already taken appropriate initial action in 2011/2012 and set on new unit heads for production and procurement. From autumn 2012 production was also working double shifts to increase the ability to deliver. And yet this is precisely where the problems arose time and again, even though TRACOE had been using ERP software since 2002, which actually should have guaranteed production planning and capability to deliver.



*Working double shifts was to increase capability to deliver*



Stephan Köhler therefore wanted to investigate more closely to see where the problems lay, and in 2013 started the project *Geschäftsprozess- und ERP-Optimierung (GEO2)* [Business and ERP Optimisation]. Köhler was assisted in this by the Frankfurt consultancy firm INTARGIA. The service provider identified all the weak points together with the departments. The initial focus was the ERP software being used, which was repeatedly held responsible for problems with delivery. The automatic small parts warehouse also did not seem to be working properly. However, closer examination revealed that the problems were much more likely to be found in unclear responsibilities, optimisable communication structures, and too-limited cross-divisional thinking on the part of managers.

The key-user concept of the GEO2 project started with these potentials. Key users were designated and trained for the ERP software in all departments. From then on they were the first point of contact for their colleagues in the event of any questions and problems. They also collected proposals for improvement in order to refine the software. In this way, “seeing the bigger picture” and at the same time an understanding of TRACOE medical’s strategic purpose were required. And not least the foundations were now laid for the fundamental changes of the subsequent years.

*Clear communications structures make work and interaction between the various departments easier*



# NEW MANAGEMENT

## The management team is extended

The support from INTARGIA also solved another of the company's problems in the medium term. After Franz Waldeck's death, Stephan Köhler realised that he would not be able to shoulder the management of the company alone for long. So in 2013 he started to look for a manager for production and development. But it was not easy to find someone to suit TRACOE. In February 2014 the first managing director, who had joined TRACOE in June 2013, left the company by mutual agreement. Fortunately the solution was then found within the family. Dr. Thomas Jurisch, the husband of Stephan Köhler's sister Catharina, had observed TRACOE's development for many years as a shareholder and managing director of INTARGIA.

In April 2014 he assumed – initially only on an interim basis – the position of second managing director of TRACOE, in charge of development, production, quality control, supply chain management and procurement. It was soon evident that now everything was just right. So on 1 January 2015 Jurisch finally became managing director. The mechanical engineering graduate with a PhD in business IT immediately concentrated on the necessary changes in production and development using his extensive experience in advising major medium-sized companies.

In July 2017 Marcus Keidl became a board member. The former commercial director had supported the course set for growth for

*Member of Management Board and  
Commercial Director: Marcus Keidl 2018*



*(From left to right)  
The Management Board:  
Dr. Thomas Jurisch,  
Stephan Köhler,  
Marcus Keidl*

several years and had, among other things, been instrumental in driving forward the take-over of the British firm KAPITEX in 2016.

## Transparency, efficient processes and modern project management

The expanded management board with Stephan Köhler and Dr. Thomas Jurisch immediately set up an extensive programme to ensure the future sustainability of TRACOE medical by means of continuous organisational and process optimisation in all areas. Taking as a starting point the strategic goal of consistently achieving double-digit revenue growth in the coming years, Dr. Jurisch focused intently on organising transparent processes and responsibilities at all

levels. Inter-departmental teams worked on the numerous projects with which the efficiency and effectiveness of all the processes would be improved. At the same time the gradual digitalisation of all the business processes commenced. With the keen international competition and the globally increasing compliance requirements of the medical technology market, process optimisation and quality management were imperative for TRACOE medical.

However, this continuous modernisation programme, ultimately an ambitious reinvention of the company, could not succeed without motivated employees who wanted to improve their work constantly. From 2013 onwards, the team leaders of the individual departments were to assume more responsibility for their departments and it was important to maintain the critical dialogue regarding the ERP system. The employees needed to be sure, however, that they could express suggestions and criticism without hesitation or fear. INTARGIA therefore had already placed the subject of “communication” centre-stage in its process of change and introduced coaching and communication training for its staff.

First of all, inter-departmental communication was improved with a new meeting structure. Priorities for new developments and product improvements were established at regular meetings between Distribution and Development. The management meeting taking place every six weeks with area managers, department heads, and management provided information for the participants who in turn passed these issues on in their project groups and working groups. Jurisch also set up a new department for process and organisational development to facilitate optimum control of the continual process of improvement.

From the beginning of 2013 the management provided details of sales, complaints, plans for improvement, and other important TRACOE matters in regular staff meetings so that the staff were always well informed about all internal company developments. In December 2014 an internal newsletter replaced the regular meetings which, however, still take place on special occasions.

*Light, friendly, modern: since the modification in 2013 TRACOE medical has new conference rooms that are used for meetings of all kinds.*



# TRACOE SHOWS PROMISE

## Big continuing education and training campaign

Production of the TRACOE tubes involved a lot of manual work and the individual work steps required different skills. TRACOE therefore underpinned the conversion to continuous flow manufacturing with internal professional development programmes so the staff could undertake as many work steps as possible. In addition to the associated flexibility in production planning, the staff also benefited from the variety of tasks. The important next step was the introduction of the internal training course *Fachkraft zur Herstellung von Tracheostomiekäulen* (specialist in the manufacture of tracheostomy tubes). The graduates received a certificate showing the qualification and providing information regarding their skills.

TRACOE also trained young people to qualify as technical sales representatives (*Industriekaufleute*), specialists in warehouse logistics (*Fachkräfte für Lagerlogistik*) and office management assistants (*Kaufleute für Büromanagement*). In 2014 the firm was also authorised as a training centre for the *BWL Industrie* (business studies) course run by the Baden-Württemberg Cooperative State University. During their studies, Bachelor of Arts graduates moved through almost all the departments of TRACOE medical.

—  
We can only  
give our best  
performance if all  
the areas of our  
life are largely in  
harmony. TRACOE  
tries to support its  
staff in this.  
—

## Extensive development opportunities

Continuing professional development was the ace in the hole. The staff from all departments were qualified on an ongoing basis through a variety of internal and external training programmes, helping them develop both professionally and personally through continuing education programmes. Success was evident not only from content and efficient staff but also from the fact that over 60% of the managerial staff started their careers at TRACOE.

In addition to “traditional” continuing education and training, TRACOE also offered its employees a separate health promotion programme of its own and a wide range of coaching measures. This involved, among other things, defining goals, resolving conflict, handling crises or developing leadership skills.

Catharina Jurisch (Cathagis Coaching) took on the professional coaching of managerial personnel and team leaders. Since the death of their father in 1990, Stephan Köhler's sister supported TRACOE in various roles and was very familiar with the staff and the corporate culture. She organised workshops on the subjects of team building and communication and mediated by means of coaching in the event of conflict.



Catharina Jurisch is  
responsible for  
coaching and  
health promotion

The introduction of the so-called 360° feedback, which Catharina Jurisch oversaw, was important for the development of the company as a whole. This method was an enormous help in the further development of management style and personality through the assessment of competences and performance from different perspectives – that of the employees, the managers or colleagues, for instance.



*TRACOE tubes are hand-crafted with the utmost precision*



#### **Total focus on the key area, production**

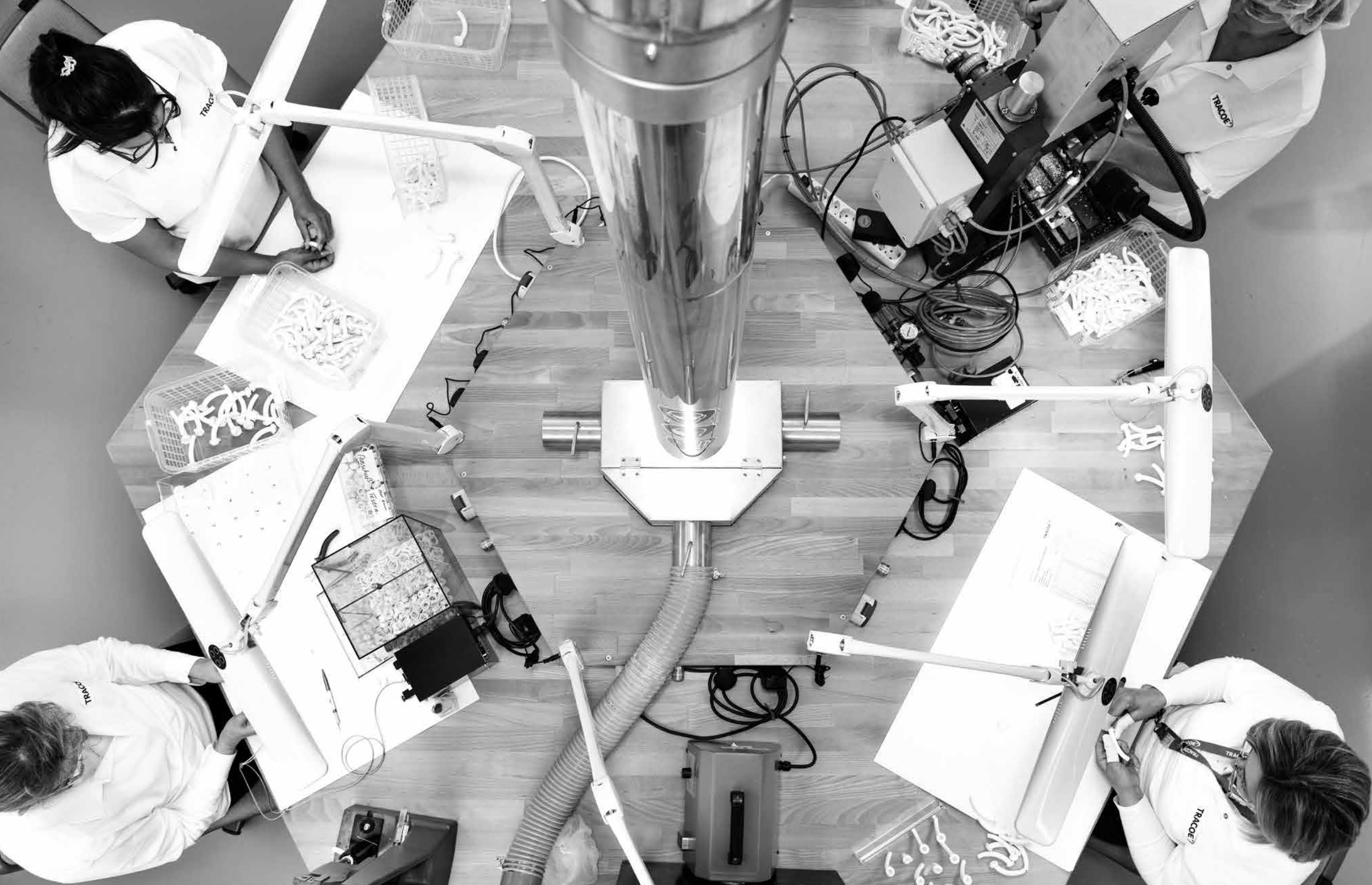
In view of the strong growth, TRACOE optimised production on a continuous basis. The need for this emerged in some quite different areas. After the two sites in Nieder-Olm were merged, Production Management also assumed the planning. This worked well in terms of content, but resulted in a plethora of tasks for Production Manager Günter Fritsche.

Therefore in September 2013, in addition to production, a separate supply chain management was set up in manufacturing and the job assigned to Normen Krob, an experienced specialist. Since then, he has not only been in charge of planning and logistics, but also operational procurement. Establishing the supply chain management meant that TRACOE was able to reduce both batch sizes and stocks in production, and, despite this, improve ability to deliver.

The prerequisite for this – and a further finding of the GEO2 project – was, however, that the production times themselves needed to be reduced significantly. The two managing directors therefore commissioned Porsche Consulting to analyse and improve the manufacturing processes at TRACOE. The consultancy firm had emerged from the Porsche crisis at the beginning of the 1990s, introducing as a result the Kaizen philosophy, which has its origins in Japan. Kaizen aims for a continuous improvement process, in which all participants accept as much responsibility as possible for their work area. The consultants were therefore the ideal partners for TRACOE – who, however, were themselves only just beginning to collaborate beyond departmental boundaries. Within a short space of time, the managerial staff around the two managing directors succeeded in strengthening communication between departments such that a joint “production optimisation” project was in fact possible. In the course of 2014, Porsche Consulting organised one-week workshops initially with teams from the pre-assembly and secondary packaging sections. The teams analysed the actual status, measured walkways and process steps, checked operations and examined the required tools and materials. They then prepared proposals for improvement to reduce the throughput

times and documented the subsequent test runs. “Road tests” revealed which ideas actually brought advantages. Questions that still remained open were noted in a “Kaizen newsletter” and postponed for the time being. Every day the participants gave feedback, formulated expectations and disappointments, and in this way controlled how the project developed.

In fact, the productive atmosphere of the workshops rapidly achieved great success. Processing time for the production of outer cannulas alone could be reduced by 19%. There were many other improvements, in detail: by skilfully adapting the quantity of solvent to the bonding process with a special tool, drying time was drastically reduced – from 20 minutes to just one minute. In the case of secondary packaging, three operations could even be completely dispensed with. Here, too, throughput times were permanently reduced and the productivity increased by 44%.



By skillfully connecting the necessary work steps in series, the throughput times of the tracheostomy tubes were reduced in production from seven weeks to one week.

The improvement process which has continued to this day, increased the capability to deliver, was reflected in falling costs and ultimately secured production on the site, because these rationalisation processes were essential for TRACOE to survive long term in the market. The necessary changes were implemented step by step starting in summer 2014, followed soon after by further workshops for reorganisation of the rest of production. Regular, in some cases daily, interdepartmental exchange has since then ensured seamless collaboration and helped to focus on the agreed goals.

*Connecting the work steps in series significantly shortened the manufacture of tracheostomy tubes*



Left: Eva Schaeffer  
Right: Adeline Renier



### Quality Management as a driver

The reorganisation of existing work processes was such a huge, arduous challenge not least because, as a manufacturer of medical devices, TRACOE was subject to very strict quality requirements. Any change in production has to be documented very accurately and set out in new operating procedures. Products and

production were examined each year by TÜV Süd (a German notified body) who also assessed whether the products were permitted to bear CE marking. They were not allowed to be placed on the market within the European Community without this certification. As an exporter to the USA, TRACOE was also subject to the regulations of the US Food and Drug

Administration (FDA), which focused even more strongly on the documentation of the work processes than its German counterpart and audited the company on site every three years.

TRACOE had begun to develop and expand the quality control department years before because of these strict requirements. The first starting point was the further development of incoming goods inspection. The quality control department was continually being expanded and concerned itself, as part of the statutory requirements, with the technical documentation, product testing and validation, qualification of equipment, industrial hygiene and product biocompatibility testing. With this quality management, the department had therefore created the conditions for all the approvals. Auditing and certification were initially time-consuming and costly but they were essential for international marketability. The company had been working with TÜV Süd as the Notified Body for years and repeatedly benefited from the strict TÜV requirements for production and documentation. They contributed to TRACOE's improvements, and were therefore part of the continuous improvement processes. Cooperation with TÜV always remained challenging, however.

Eva Schaeffer took over management of quality control at the end of 2013. There were now seven employees working in incoming goods inspection, quality control and assurance, hygiene or regulatory affairs. At the end of 2016 quality management (QM) was finally separated in terms of personnel and organisation from product-related quality control. Adeline Renier was appointed the quality management officer.

During the preparations for the new EU Medical Device Regulation (MDR), which came into force on 25 May 2017 with a transition period for existing certification up to 25 May 2020, quality management was fundamentally reorganised early in 2018 so as to be optimally prepared for the upcoming significant requirements involved in certification. During this reorganisation Eva Schaeffer assumed responsibility for the task of making the marketing authorisation documents MDR-compliant. At the same time, numerous other internal functions were revamped so that the organisation and production processes in general remained certifiable in future.

### Innovativeness becomes top priority

TRACOE also continued to attach enormous importance to a high rate of innovation. True to the motto “Quality by People for People”, the company ultimately wanted to contribute to improving the quality of life for patients and the treatment success of physicians in the long term. Intensive exchange with doctors and users was a recipe for success – in this way products were continually improved and new developments pursued. And this is the reason that TRACOE leads the field in developments for tracheostomy today.

In the last 15 years alone, TRACOE made over 30 patent applications, of which 14 patent families were granted in a complex process. Further development of the speaking tube was among the most important innovations of recent years. The problem with fenestrated tubes, which facilitate speech, cropped up time and time again: in certain postures, the side with holes pressed on the trachea so that the airstream no longer passed through the vocal chords. Dr. Ralf Schnell, TRACOE medical's head of development, found a perfect solution with what was actually a simple idea: he made further openings on the opposite side so that the air could exit in any position. For this simple yet effective innovation, which distinctly improves

the patient's quality of life, Dr. Schnell even received the German Innovation Prize for out-of-hospital intensive care (*Deutschen Innovationspreis für außerklinische Intensivpflege*), which was awarded for the first time in 2013 at the congress of the same name in Brandenburg an der Havel.

The same year TRACOE also made a patent application for the “smart Cuff Manager”. It maintained the internal pressure of the cuff which closes off the trachea towards the lungs to prevent undesirable secretions from entering the lower respiratory tract. The innovative product reduced complications such as ventilator-associated pneumonia and improved the successful outcome of treatment. The simple application and the visual confirmation of the optimum cuff pressure made the job easier for the nursing staff in hospitals and also in the HomeCare sector. In 2014 TRACOE enhanced cuff pressure management with the TRACOE *procuff*® S suction pump.



Dr. Ralf Schnell  
with his award – the  
“German Innovation  
Prize for out-of-hospital  
intensive care”



The development department had proved to be hugely effective many years earlier and was also continually being expanded due to the strong growth of TRACOE medical. Seven project managers were now dealing with research and development – several laboratory rooms with modern equipment were available for their work. Following the relevant training programmes, two employees from production moved to the development department where they ensured close interaction with manufacture. Following the restructuring of production, the development department, together with Porsche Consulting, examined the potential for improvements in the work processes.

The department also maintained contact with science and clinical practice. The network with doctors, nursing staff and universities was further extended in close cooperation with sales. “Research” and “Development” were separated in 2017 due to the large number of tasks and also to ensure that both areas could be handled intensively. As head of research, Dr. Schnell handled all the research topics and in order to do this was given the necessary freedom to observe market developments and to develop contacts with universities, researchers and physicians worldwide. As head of development,



*Research & Development work continuously on innovations and improvements*

however, Dr. Christian Wahnes was responsible for all TRACOE's concrete developments. A transfer group with three employees made sure that development and production were coordinated at an early stage of product development.



*All TRACOE products are rigorously tested before being launched on the market*



### Significant expansion of the sales department

Sales had already been expanded significantly prior to the move to Nieder-Olm, which strengthened export in particular. The number of sales staff increased significantly with the result that not only hospitals in Germany but also international distribution partners were much more intensively supported. Joint visits to customers and local hospitals fostered the bond between TRACOE and end-customers – increasingly also abroad, where the company's sales staff trained the employees of the partner companies with regard to new products or modern sales strategies. Each year Stephan Köhler personally visited several foreign customers, going to see each foreign retailer every three to five years.

In previous years TRACOE had constructed a new management structure for sales. With the appointment of Jörg Altenburger, who initially joined TRACOE as a member of the sales force in 2007 and then became foreign sales manager, a personality who was familiar with sales in all its facets assumed the overall sales management on 1 January 2015. In 2014 Ortrud Schön joined the company as domestic sales manager while Rimm Elfu, who had joined TRACOE as a member of the sales force for USA/Canada and the Arabian region in 2011, took over foreign sales.

A very special success story for foreign sales occurred in the Arabian region. Between 2013 and 2015 TRACOE, through its local retailer, won the biggest invitation to tender in its history: they supplied goods for the hospitals in the Gulf States to a value of over EUR 2 million.

*The large retailer network makes TRACOE a successful global provider of tracheostomy tubes*



From 2012 onwards, the company had also been developing contacts with an importer in Iran through a business partner. The first small orders followed in 2013 and, after a round trip to many of the country's hospitals in 2015, TRACOE received orders for the percutaneous dilatation set in such large numbers that at the end of 2017 production and logistics had reached their limits and were only able to deliver by working overtime and at weekends.

The International Distributors Meeting, which took place for the first time in November 2014 became a resounding success for sales. TRACOE invited all the

international dealers to Germany, showed them production and organised a large programme in Frankfurt. The date was also linked to the annual MEDICA trade exhibition taking place in Düsseldorf, for which the majority of dealers had travelled to Germany in any event. The second Distributors Meeting in 2016 was also a complete success. The dealers learned more about TRACOE as a company and were able to take the opportunity to talk to the management. The idea of expanding contacts with dealers in this way had been an unqualified success.

*A very special event every time: the International Distributors Meeting. Here the participants in 2016.*



*As managing director in Salzburg, Jörg Altenburger expands sales in Austria and southern Europe*

Sales in the HomeCare segment were reorganised at national level in 2013. In order to boost sales of the comparatively expensive TRACOE products that required intensive support with tailor-made advice, a significantly enlarged team trained the distributors, service providers and health insurers in the application of the TRACOE product portfolio from then on.

As reaction to the market trend towards centralisation made access increasingly difficult for niche providers of special products, in March 2014 TRACOE concluded a distribution partnership with Fresenius Kabi Germany for the out-of-hospital segment. However, this strategic cooperation did not prove successful and was therefore dissolved in 2016. The company

succeeded in winning the majority of its customers back again.

In Germany the HomeCare market was under continued price pressure due to the flat rates for service providers implemented by the health insurers. It was the larger service providers in particular who reacted by entering the market with their own cheaper products. Nevertheless, it was still strategically important for TRACOE to have a presence in the HomeCare segment, not least because it was also becoming increasingly important internationally.

In early 2018 Rimm Elfu ultimately assumed overall management of sales while Jörg Altenburger developed sales in the important region of Austria and south-east Europe as managing director of the newly founded TRACOE medical GmbH Austria with its head office in Salzburg.



*Rimm Elfu is general sales manager at TRACOE*



*During the video shoot for the multiple-award-winning image film "Quality by people for people"*

### **A branding that makes an impact**

In 2013 TRACOE had already set up its own marketing department under the direction of Marina Grundmann. This was a strategic milestone for the company – and at the same time also a crucial step, as the expertise required for this specialist area with its various disciplines had to be acquired within a very short space of time. Since Stephan Köhler joined the company, a familiar but external Frankfurt agency had overseen and implemented the marketing and the corporate image. Marina Grundmann now set herself the challenge of completely restructuring the new department. She set up her own data pool, gradually took over the tasks of the agency, and from then on controlled everything in-house. She soon had her own network of graphic artists, printers and media agencies.

But above all the marketing department needed to be integrated in the existing and radically changing structures and processes. Together with sales, Marina Grundmann established the materials which the sales force required and at the same time made sure that TRACOE medical had an impressive and successful presence at trade fairs. Design guidelines and the corporate design manual were updated to strengthen the visual recognition value of the "TRACOE" brand with its individual product groups – and convey the corporate vision and values with clear messages and stories.

The new image film "Quality by People for People", which had even received multiple awards, proved to be one of the greatest successes in marketing. Encouraged by this success, TRACOE has since focused increasingly on moving images to present their products on the one hand but – for training, for instance – also to explain them simply and in a user-friendly way. All the videos were now created in-house, and gave the company a clear competitive edge in Germany.

TRACOE was also accomplishing great things in media work, Web and social media and thanks to its marketing department had a successful, professional and wide-reaching presence on a variety of channels, rarely found in this form within the industry. For example, large-format articles in the regional and specialist press regularly drew attention to companies and brands, and Facebook and YouTube were now also important components of external communication.

Today, the marketing department employs five specialists from communications, design, and graphics. The department will also in future inform its customers of product developments and current developments using important Internet channels – and also continue to develop the platforms in Web 2.0.

*(From left to right)  
At the award ceremony of the World Media Festival: Karin Strasser and Marina Grundmann together with the organisers*



### Conflicting priorities, sales, development and production

TRACOE has always been largely shaped by sales. New product ideas and all the market information regarding products and customers has been gathered by this department and then launched as projects. However, due to its strong growth, but also the strategic plans to develop internationally into a leading supplier, the company was getting ever closer to reaching its limits. It reached the point where important projects and ideas were literally getting blocked and in some cases the overview of the relevant project status was even lost. Conclusion: sales was simply overburdened by the enormous volume of tasks and responsibilities; there was no interface between the development department and production; and there were no structured processes to evaluate, prioritise, and finally start development projects.

TRACOE's continuous growth also required further professionalisation of brand management and sales strategies. In 2015 the "sales support" team began their work. Publications, field and user reports on subjects relating to TRACOE products were initiated via the national and international network. An extensive campaign management – dovetailing of press relations, specialist publications,

lectures, training courses and workshops for the TRACOE product lines – successfully imparted the message that a tracheostomy tube was not merely a product but an essential component of a therapeutic concept. By the end of 2018 Gerlinde Müller-Daniel, who had previously worked in sales, was managing the department.

If the main purpose of sales support was initially to take the pressure off sales and to support sales by focussing on customer information, TRACOE went one step further in April 2016 and set up a separate product management department as a contact point between sales and the development department. Wolf Schürmann became head of this department with currently two staff. Schürmann came from the TRACOE sales force where he was responsible for the region Eastern Europe/Asia. His first task in product management was the introduction of a new product group, which included commercial products under the name "select". The starting point in 2016 was the possibility of obtaining a worldwide licence (outside the USA) for the distribution of an innovative balloon dilatation catheter for the ENT segment. Taking this product as a basis, TRACOE built up a range of high quality commercial products from selected manufacturers.



*From left to right:*

*Sales support:  
Gerlinde Müller-Daniel,  
Julia Bohm,  
Maïke Schönfeld*

*Product management:  
Wolf Schürmann,  
Christine Köstner,  
Margaryta Kuznyetsova*

The new "product management" interface department coordinated the planning and development of new products. Schürmann and his team focused more sharply than sales, the development department or production on the product lifecycle and looked at the entire TRACOE product portfolio as a whole. The interdepartmental cooperation and communication that began in 2012 was particularly in evidence here. Successful growth was not possible for the management team of Stephan Köhler and Dr. Thomas Jurisch without this cooperation.

# KEEPING THE FUTURE IN SIGHT

*Managing Director of MC Europe: Richard van Goor*



## **Investment in MC Europe**

In September 2011 TRACOE had acquired just over 75% of the Dutch company MC Europe medical products. Managing director and founder Richard van Goor had formed MC Europe in 2009 from the company Azimed, where he had developed the intensive care division.

The business suffered from too little investment, however. For this reason, he acquired the intensive care section from Azimed in 2009 and founded his own commercial enterprise trading under the name MC Europe with its head office in Weert near the Belgian border. In consultation with his partner companies he now extended the commercial area to all the Benelux States, focusing his range on the premium segment for intensive care, anaesthesia, and the emergency department.

The company was already a customer of TRACOE, had grown strongly since its founding and with four members of staff had now reached the limits of its capacity. Richard van Goor met Stephan Köhler at a training session in Nieder-Olm. They both soon noticed that the philosophies of the companies had a lot in common and so, after intensive discussions, van Goor was persuaded about the possibility of cooperation. In 2011 he sold 75% of his company to TRACOE and thus became the first subsidiary of the tracheostomy specialist.



*The staff at MC Europe, 2017*

It was a transaction with great advantages for both sides. MC Europe was able to take over the exclusive TRACOE distribution in the Benelux countries immediately. As managing director, van Goor also retained a great deal of freedom in decision-making and benefited from the infrastructure and the strategic management of the German parent company. For TRACOE the step provided a model for further acquisitions in order to expand distribution in other countries. The positive experience with MC Europe reinforced Köhler's opinion that, in addition to strategic considerations, partnership solutions on equal terms and with similar corporate philosophies played a key role.

In the beginning, the young and much smaller MC Europe had neither a financial control nor a procurement department of its own. The entire operational business was handled by two sales representatives and two office staff. Through the profitable TRACOE with its particular experience with strong growth, van Goor now obtained the financial and organisational support to expand the business and hire personnel. The number of employees at MC Europe rapidly increased and the company's sales showed 400% growth within five years.

# INTERNATIONAL EXPANSION

Managing Director of KAPITEX: Ian Worthington



## Acquisition of KAPITEX Healthcare Ltd.

KAPITEX Healthcare Ltd., founded in Wetherby in the north of England in 1991, is one of the market leaders in the United Kingdom for the development and manufacture of medical devices for tracheostomy and in particular laryngectomy. The company had for years enjoyed an excellent reputation for outstanding product quality and good service.

For over 20 years, the profitable company had already been an exclusive TRACOE distribution partner for the United Kingdom. The opportunity for acquisition did not arise until 2016 when both the owner and two directors, each with a stake in the company of around 10%, wanted to retire for reasons of age, and it was decided that the step was to be an important one for TRACOE. Köhler and Jurisch finally acquired KAPITEX after lengthy negotiations with the owners, together with Ian Worthington, the third director of the company. The XTR Group held 77.5% and hence Stephan Köhler as shareholder in the group, Dr. Thomas Jurisch acquired 10%: Ian Worthington, who also remained in the company as managing director, held 12.5%.

Among other things, KAPITEX marketed its own products in the airway management segment, i.e. maintaining and ensuring respiratory function in tracheostomised and laryngectomised patients. The company also offered special ENT products in the field of laryngology under the slogan "Airway Intelligence".



Head office of Kapitex  
Healthcare Ltd. in  
Wetherby, England

It was therefore clear to all concerned that by purchasing the company, TRACOE could above all enhance its competence in the field of laryngectomy, as well as gaining exclusive access to the British market. Köhler, Jurisch and Worthington also hoped for considerable synergy effects in the product ranges of the two firms. KAPITEX, however, had in recent years suffered from a major investment backlog, so that the need for an investment programme was already apparent when the purchase occurred.

The company currently had approximately 30 employees. The sales of TRACOE products made up about 30% of the entire KAPITEX turnover, the remaining 70% being attributed to the marketing of their own products and the sale of commercial products. Worthington, Köhler and Jurisch saw development potential particularly in export, as turnover here was below 15%.

### Together we are strong – the group of companies

With the two subsidiaries in the Netherlands and Austria and the sister company in England, today TRACOE is a European group of companies whose aim is to successfully maintain a presence in its markets in the long term. The XTR Group GmbH formed the framework for this under company law. Stephan Köhler had founded it in 2003 – at the time together with Professor Waldeck – in order to invest in companies in the medical devices industry. The first investment was a 50% share in medi1one medical Grosshandels GmbH in 2003. After five years of strong growth the shares were sold again at a large profit.

At this point Köhler also acquired Waldeck's shares in XTR, thus becoming sole proprietor. He finally incorporated TRACOE medical GmbH 100% into the XTR Group in 2013. At that time TRACOE itself already owned 75% of the Dutch MC Europe medical products and in 2016 XTR acquired 77.5% of the British KAPITEX.

With the XTR Group Köhler, as a family businessman, invested in an international company from the medical devices segment. The company was to be further developed true to the TRACOE philosophy

in its own name and with managing directors from the region who were associated by shareholding. XTR therefore constituted a holding company for the group.

The long-term strategic plan for the current companies in the group was to make TRACOE a “centre of excellence” in the field of tracheostomy, while MC Europe assumed this role in the respiratory care segment, and KAPITEX in the laryngectomy segment.

Meetings and training programmes were taking place on all levels to network the three companies to make a viable group and encourage dialogue. Reciprocal visits and inviting all the employees from England and the Netherlands to a communal Christmas celebration in Nieder-Olm enhanced the feeling of solidarity. At senior executive level this was in any case no problem because all four individuals shared similar values and corporate ideals.



*The management members at the  
Christmas party in Mainz, 2017*

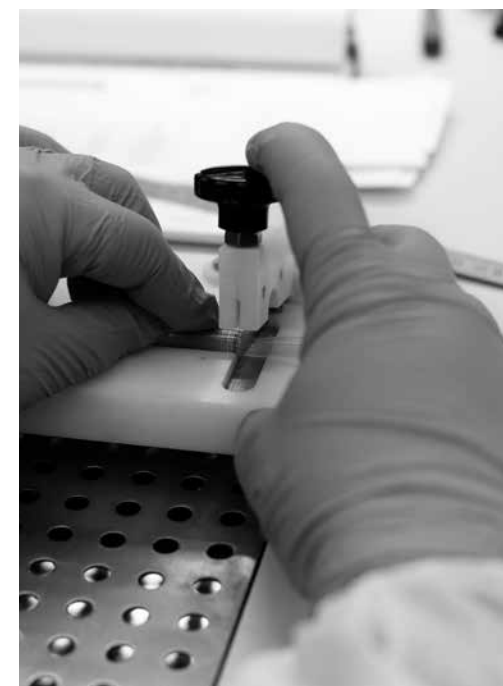


## NEW FACTORY NEW MATERIAL

### TRACOE medical focuses on silicone

It was one of the most exciting challenges in the history of the young firm – and with an investment volume of around EUR 1.3 million, also one of the biggest: in 2017 TRACOE set up a new factory on the Nieder-Olm site for the production of tubes made of silicone. This material is particularly soft and flexible, yet very kink-resistant and, thanks to these properties, also particularly gentle on the mucous membranes of the trachea.

*Manufacture of TRACOE silcosoft tubes*



However, TRACOE was entering completely uncharted territory in some areas with silicone production – the company would first have to painstakingly acquire the expertise required for working with this material. As the silicone oil produced in the processing of silicone renders the processing of conventional plastic tubes impossible, TRACOE was left with no alternative but to have its own factory. Here for the first time the company made the complete tube without the supply of individual parts. Development, manufacture, product management, sales support and marketing needed over two years to plan the first silicone products together and get them off the ground. Production planning and the products themselves, however, required complex approval and certification procedures at all stages.

*An employee inspecting TRACOE silcosoft tubes*



*The small parts of the TRACOE silcosoft tubes are made in the silicone press*

All in all, the project needed significantly more time and financial investment than originally planned, but it was a complete success: the marketing of the new product line TRACOE silcosoft from the product group TRACOE *kids* commenced in the summer of 2018 with products for the care of neonates, infants and children. With these products, the company increased its portfolio for children and neonates, which also included products such as neck straps and heat/moisture exchangers, in one fell swoop from two to ten tubes. The quality of the new products was reflected in many details. The straps to secure the cannulas to the neck could now be closed with one hand, leaving the other hand free to hold and calm the child. TRACOE also offered a complete range with different lengths of tube, and flanges and cuffs to fit.

The new silicone production and extension of the range for neonates, infants and children meant a quite significant improvement in their provision. At the same time the company therefore strengthened its position on a global, highly specialised market.

With this TRACOE underlined its claim of being a global leading supplier of products in the fields of tracheostomy and laryngectomy. It was even more important, however, that the new products could serve an important and highly specialised market for this target group. There were only a few suppliers worldwide for children's tubes with a similarly wide range.

## TRACOE *kids* – the smaller the detail, the greater the value

Sometimes the greatest success comes in small sizes. In 2018, the TRACOE *kids* range was relaunched with two product lines: the well-known TRACOE mini and the brand-new TRACOE silcosoft. Both lines include tracheostomy tubes designed especially for neonates, infants and older children.

The TRACOE mini is a soft, thin-walled, but stable PVC tube that does not contain any DEHP. The flange has a sloping lower surface to optimise the anatomical fit.

The TRACOE silcosoft is a very soft flexible silicone tube with spiral reinforcement, supplied with or without a cuff. Special features include the optimal shape of the neck flange and the patented specially reinforced eyelets. The tried-and-tested ring obturator is particularly practical. The grip at the end ensures that the tubes can be inserted easily and safely despite their small size and different materials. Extensions, neck straps, heat/moisture exchangers, and special compresses are available to use with the TRACOE *kids* tubes.





*Inauguration of the new logistics centre in 2018*

#### **Future projects: logistics centre and representative office in the Middle East**

Parallel to developing the cutting-edge silicone production for the company, TRACOE invested in a second important project in 2017 and 2018: in June 2018 the company opened its new, modern logistics centre in Nieder-Olm. TRACOE thereby increased its storage space to 3300 m<sup>2</sup>, and through the consistent availability of goods ready for shipment, TRACOE also created the conditions for meeting demand worldwide as quickly as possible.

At the same time, as a result of moving stock to the new centre, TRACOE gained valuable space in the company headquarters that was urgently needed for the production, research and development

facilities. Meanwhile all the finished products and some of the commercial products were provided using the “supermarket principle”. The staff took the ordered goods from the shelf and put them in a virtual “shopping cart”. An electronic control process checked the stocks of each individual product at any time and gave a signal as soon as the number fell below the specified minimum quantity.

The fact that TRACOE had been working hard to increase the world-wide demand was already evident in early 2018 from the opening of a new representative office in Bahrain. With this new mainstay in the Middle East, TRACOE was able to provide even more intensive support for local traders and customers. Stephan Köhler was

convinced: “The markets in the region – from the United Arab Emirates to Iran – are among the fastest-growing markets in the world. We want to be well positioned here in future”.

For TRACOE medical the investments in the logistics centre and silicone production, the expansion of the group by acquiring KAPITEX, the new distribution company in Austria, and the representative office in Bahrain represented important strategic steps towards global growth. Since the merging of the two sites in Nieder-Olm, TRACOE had finally developed from a small enterprise in a niche market into an exceptionally innovative and dynamic medium-sized company. Today, TRACOE medical GmbH has around 215 employees, and in 2017 generated EUR 22 million sales. The XTR Group generated a total turnover of around EUR 30 million. The modernisation in all areas, the integration of the team, the well-oiled management, and the generally tangible spirit of optimism show: TRACOE is well prepared for the future.



*An employee fills the “supermarket” with products*



# YESTERDAY, TODAY, TOMORROW

## Big plans for the future

If we look back at the beginnings of the company, we are impressed again and again by what has resulted from Rudolf Köhler's original idea. What was once a small "hole-in-the-wall company" with which the founder – in addition to his actual profession – produced and sold tracheostomy tubes, is today a world-wide sought-after developer and manufacturer of medical devices for patients with tracheostomies or who have had laryngeal surgery. We still have much to thank Rudolf Köhler for with his vision of improving both the quality of life for patients and the treatment success of medical staff. "Quality by People for People" – this has been the case for 60 years and will also guide us in future.

We need a commercially strong company in order to realise our vision amid growing global competition. For this reason we are on course for growth that will continue to characterise TRACOE medical in the years to come. Our ambitious goal is to double turnover every five years through organic growth. Product development, production, sales, marketing and administration – every department sets itself this task, every day.

*Production and administration  
under the same roof since 2013*



BY PEOPLE

QUALITY

FOR PEOPLE

However, this strong growth needs space. In recent years we invested heavily in the Nieder-Olm site, extending it further, yet time and again reached our limits with increasing turnover. We are considering two options in the medium term, in order to have more space. One possibility is to purchase further real estate in Nieder-Olm. TRACOE would acquire additional property in the vicinity and could set up new production and storage capacity there. The other option is to erect a new “green-field” plant and relocate the entire company elsewhere. The decision for one or both alternatives will be made in the next few months.

#### Global competitiveness

We can only hold our own in global competition and simultaneously continue to grow because of our high level of innovativeness. This is why TRACOE medical's development department is to be significantly expanded once again in the next few years. Our objectives here are to introduce innovations on the medical technology market at regular intervals, continue to consistently improve the products, and systematically complete the individual product groups.

Moving into silicone production, which has already been accomplished, is a mile-



*Made by hand: the  
new TRACOE silcosoft  
silicone tubes*

stone in this direction. It significantly increases our development opportunities thanks to the new material, with the result that TRACOE medical expects a strong growth spurt. The successful introduction of the silcosoft tubes encourages us to continue along this path.

One of our strategic goals in the next few years is for our products to have a presence in hospital ENT departments similar to that in intensive care and anaesthesiology. So we are intensifying our activities with a view to developing new products for respiratory care. With KAPITEX, our sister company in the United Kingdom, we have a competent partner at our side for this.

#### Medical Device Regulation: challenge and opportunity

The EU Medical Device Regulation (abbreviated as MDR), which entered into force on 25 May 2017 with a transition period of three years, presented medical device manufacturers with a huge challenge, which we believe will strongly affect the entire industry. TRACOE has been working intensively for a long time to prepare for the MDR and is optimally prepared to overcome this huge regulatory hurdle, both in terms of personnel and organisation. As implementation of the MDR involves a great many changes and therefore also high costs, many small suppliers will struggle to satisfy the new requirements for certification. It can therefore be expected that the number of medical technology suppliers will decrease sharply overall. The industry's major companies in particular will benefit.

TRACOE medical has grown strongly in recent years and has developed very efficiently in all areas. We can therefore see the opportunity in the MDR and imminent market concentration to increase our market share and perhaps even to continue to grow through acquisitions. So on no account can we let up with our efforts, our efficiency, our quality, and our innovativeness.

#### Global growth

In previous years TRACOE medical once again recorded significant growth in the international markets. The basis of this excellent success in sales is a trusting and good relationship with our distribution partners all over the world. TRACOE will continue to focus on this success model in the future and also expand the network of partners in regions where we are not yet so strongly established. Some out-of-the-ordinary paths are also conceivable here, such as currently our representative office in Bahrain with which we were able to establish a strong foothold in the region.



#### The XTR Group as a reliable support

XTR, the parent company of TRACOE, MC Europe and KAPITEX, is of particular importance in our plans for the future. In the next few years the three partner companies will increasingly develop into centres of expertise for tracheostomy (TRACOE), laryngectomy (KAPITEX), and airway management (MC Europe).

The individual companies have strong financial and strategic support in the holding XTR Group. The aim of these holdings is to further develop the companies under their own names and sustainably develop a group of companies operating at global level. The XTR Group will therefore acquire further companies in future if the opportunity arises and fit them into the group.

The XTR Group is not least a further commitment to entrepreneurship. The managing directors of the subsidiaries should if possible have a stake in their companies, and Stephan Köhler may oversee all the shareholdings in an entrepreneurial capacity from within the management or later perhaps also from within the supervisory board of XTR.

TRACOE SAYS  
A BIG 'THANK  
YOU'

TRACOE is a third-generation family business. Independence is important to us. As a family business, we stand for humanity and honesty towards our employees, customers, suppliers and partners. And this will not change in the future.

We were only able to consistently develop our high quality and innovative premium products and place innovations on the market through development and production on the German site. The production location in Germany is therefore an important part of our strategy of growing sustainably with quality but without losing the character of a family-run, medium-sized enterprise in so doing. TRACOE medical will stand for quality "Made in Germany" in future. The new production facility for silicone products in Nieder-Olm is a clear indication of this.

We would like to express our sincere gratitude to all the staff at TRACOE who have played a part in this success story with their commitment and motivation. Our thanks also go to all our customers and business partners for their trusting and loyal cooperation – often spanning decades. It is therefore with great pleasure and positive anticipation that we look forward to a common future and eagerly await the next milestones and success stories of TRACOE.







