Germany is a vital test market for foreign medical technology companies. Turnover potential is high and exports are strong. There are numerous new investment opportunities, from prosthetics and software to smart labs.

Cinematic Volume Rendering Technique (VRT): a research visualization technology that here enables a high-resolution, anatomical image of the brain, merged with colorful tractography data.

Robot Revolution: From production through to healthcare, robots are taking over
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The Power of Tiny: Germany is in the hot seat of the global semiconductor market
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Healthy Outlook

Germany is one of the world’s leading medical technology markets: the revenue potential for companies is high and exports are strong. This is why it is a key market for foreign medical technology companies, with a myriad of opportunities.

The robot gripping arm from the Canadian company Kinova Robotics is a boon for wheelchair users who have little or no movement in their arms. With the arm, they could, for example, open the refrigerator, take out a bottle, pour a glass and drink something without assistance.

Headquartered in Quebec, Kinova is one of the most successful growth companies in the medical technology (med tech) industry in Canada. After operating in Germany for several years, the firm opened a sales department there at the start of 2017. “Germany is the leading market in Europe,” says Peter Fröhlingsdorf, MD of Kinova Europe in Bonn. “The revenue potential is great and the customers more demanding than elsewhere. If the Germans are impressed by a product, that is a good argument for sales in other countries.” Fröhlingsdorf sells the robotic arms to specialized medical centers, whose technicians adapt the product to their customers’ wheelchairs. “We get a lot of feedback and are in close contact with the retailers. This cooperation with the technicians is by no means as common in other countries as it is in Germany. It requires effort. On the other hand, it allows us to make our products the very best they can be.”

An important test market

There are several factors that make Germany highly attractive to foreign medical technology companies. The country’s healthcare market is one of the largest in the world, worth €337bn. Its med tech market is the largest in Europe. Furthermore, many well-trained physicians work in some 2,000 hospitals nationwide, as well as in university clinics and research institutes. Meanwhile, highly-qualified researchers and engineers are driving
innovation in the industry. The German market thus offers a good basis for developing and launching new products and processes. "Germany is regarded as an important reference market for the introduction of innovative technologies," says Joachim Schmitt, MD of the med tech industry’s association (BVMed).

At the moment, the German healthcare market is growing by almost four per cent per year, which is stronger than the German economy as a whole. Many factors are responsible for this growth: for example, the number of elderly people has dramatically increased and is expected to reach 10 per cent of the total population by 2020, with up to 3m people needing care rising to more than 4m by 2050. The demand for nursing technology is correspondingly high. Digitization has also spurred growth: an electronic health card has been recently introduced and patients are more open to using e-health services. According to the IT industry association Bitkom, 90 per cent of Germans already use health apps or would do so in the future and 75 per cent would like to receive test results in digital form. The German market for mobile health was valued at €3bn this year.

Market insights
Medical technology is one of the most important sub-sectors of the German healthcare market. Med tech imports have risen from €9.5bn in 2005 to more than €15bn per year. Most med tech companies in Germany are SMEs employing less than 250 employees; a large proportion are internationally successful and the average export rate is 64 per cent.

But if you want to gain a foothold in the German market, you need to adapt to the country’s complex healthcare system. In Germany, most citizens have some form of statutory health insurance (GKV), which covers more than 70m Germans. Most of the remaining 12m Germans have a private health insurance. The GKV’s medical service checks whether a new product fulfills certain criteria before offering cover. “At any rate, you need someone here in Germany who is very familiar with the system,” says Kinova Germany’s MD Fröhlingsdorf.

The Federal Joint Committee (GBA) also plays a key role for med tech companies: it defines the principles according to which the statutory health insurance funds provide medical cover to their members and is involved in the practical implementation of legal regulations on medical technology. Recently, European legislators have revised the requirements for new medical products: manufacturers of high-risk products in particular will have to demonstrate more clearly the extent to which they are generating a greater benefit or lower cost than conventional technology before the health insurance funds will cover the costs.

Med tech ecosystem
"How exactly this new process of testing will look in practice is still to be seen,” says Sebastian Gaiser from the American medical and pharmaceutical group Johnson & Johnson, which operates several production plants in Germany (see interview). "It is therefore even more important for med tech companies to get involved in the process and to establish a dialogue with the investigating bodies. This applies irrespective of the size of the company.” It is particularly helpful for newly-established medium-sized companies to be located in one of the many med tech clusters around the country, as private and state funding is relatively easy to obtain where companies, research institutes and clinics work closely.

The density of high-caliber research institutes in Germany is an important draw for foreign companies. The institutes are familiar with local conditions and can support partners in R&D. The Fraunhofer Institute

»If the Germans are impressed by a product, that is a good argument for sales in other countries.«

Peter Fröhlingsdorf, Kinova Europe
for Production Technology and Automation (Fraunhofer IPA) in Stuttgart is one of the largest, with around 1,000 employees, including some 80 med tech specialists. The experts are primarily engaged in the field of orthopedics and laboratory/clinical automation and cooperate with 30 other Fraunhofer institutes. “In this way, we get expertise at the highest level on many special topics where there are intersections to other research areas,” says Urs Schneider, who is responsible for medical engineering at Fraunhofer IPA.

In addition, the researchers work closely with university hospitals across Germany and abroad, especially in the U.S. market. “Medical technology is a global industry, so we are also doing research globally,” says Schneider. In addition to their technical expertise, Schneider and his colleagues know the regulations in their home country, with all their specialties and ongoing changes: “You need both in medical technology research and development: know-how at the highest international level and at the same time knowledge about the situation in the local market.”

**Academic research is key**
The medical engineering department of Fraunhofer IPA works largely on behalf of industrial companies. The researchers create feasibility studies, build and test complete prototypes of medical devices such as prostheses and implants or machines on test stands and assist companies in the evaluation of benefit calculations, taking account of...
Sebastian Gaiser, responsible for German government affairs at the U.S. Medical and Pharmaceutical Corporation Johnson & Johnson, works at the Group's Berlin office and maintains contact with politicians. He encourages medium-sized companies with foreign roots to actively participate.

Mr. Gaiser, to what extent is the German medical technology market special when you compare it to other markets?
In Germany, almost all citizens are covered by health insurance and do not pay for the majority of medical services themselves. If a legally-insured patient is treated, whether as an inpatient or outpatient, the bill for the treatment ends with his health insurer. Those institutions therefore have a great influence on which treatment methods and medical products are used. It is usually difficult to get something they do not want on the market. It is therefore important to understand the interplay of health insurance companies, doctors, clinics and politics.

What does this mean for foreign medical technology companies?
They have to deal with the market at an early stage and intensively familiarize themselves with the habits. This is now more important than ever. Legislators and health insurance funds have been pushing for cost savings. You cannot cut costs by making people redundant because of public opposition. A law that has recently come into force is primarily aimed at reducing material costs. As a result of pressure from the hospitals, the profit margins for medical technology devices, which are already under pressure, are likely to continue to fall. This can have an impact on the innovative power of our industry.

That doesn’t sound particularly appealing, does it?
Let’s say the framework is not getting easier. But Germany has been and still is an important market because of its size and the available know-how. The plethora of high-caliber physicians, research institutes and companies offers foreign firms many opportunities to develop innovations in partnership. This is yet another feature of the German market: partnerships and alliances are more important here than in other markets. The collaboration between research and industry is especially close in the many medical technology clusters. Anyone who wants to be a world leader in medical technology must be represented here in Germany. But you have to learn to play according to the rules.

Many foreign medical technology companies start with a small team in Germany. How can they contribute to political processes?
Small and medium-sized companies are often important innovators for our industry and it makes sense for every firm in our industry to make themselves heard and take an active part in the political process. Companies can contact local politicians, for example, and inform them about what they are doing. Many politicians here are willing to acquire more detailed knowledge about medical procedures and medical technology. In addition, they have an open ear for the establishment of innovative companies. In the current situation with new laws and EU regulations, the opportunity is favorable to active participants.

»Come to Germany to be a world leader«

Sebastian Gaiser, Policy advisor at Johnson & Johnson

Production of prosthetic limbs at the world-leading orthopedic technology manufacturer Otto Bock in Duderstadt, Lower Saxony. Powered by myoelectricity, this “art hand” can move four fingers to perform very small movements.

Photo: Christian Bunker/Dief
»The reputation of the German market is high: whoever makes it here can make it anywhere.«

Thomas Krause, MD of Amplitude Germany

Germany’s regulatory requirements. “Much of this is secret contract research, which we do not discuss with third parties for competitive reasons,” says Schneider. “This is a difference, especially to the U.S., where companies either do research alone or publicly collaborate with universities or institutes.” Finally, the institute has supported a foreign company to develop a machine for the fully automated examination of blood bags for the German market, which makes the error-prone manual examination superfluous. “Until now there was no such machine on the German market,” says Schneider. “It’s a completely new development.”

In addition to such commissioned projects, the Fraunhofer institute is developing its own innovations that med tech companies can use under license. Recently, a group of bi-onics experts and medical technicians have developed a tool that can be used to drill not only round but also square holes for non-slip anchors. The technology is interesting for all types of anchors, regardless of the industry, but especially for the medical sector. A company is already testing the now patented technology for use with artificial hip joints. A special drill could hollow out a patient’s thigh bone in order to optimally anchor the shaft of an artificial hip joint.

The French knee and hip prosthesis manufacturer Amplitude is familiar with the German research landscape. Since the introduction of the endoprosthesis registry five years ago, for example, all details of knee and hip operations are documented, especially after what time period a prosthesis breaks and has to be replaced. To date, around 500,000 implants have been recorded and the number of participating clinics is growing. “The register is very interesting for us as a manufacturer of high-quality implants,” says Thomas Krause, managing director of Amplitude’s German subsidiary. “Our distribution works on a scientific basis, and the vastness of the database of the German registry is an exception in a global comparison.”

Operating in Germany
Amplitude employs 260 people worldwide and is the number two for hip and knee implants in France. Its German sales and marketing subsidiary employs nine people. The local market is one of the most important worldwide, and is vital to the company’s plans for growth. “The German market is highly competitive and the price level for our products is at the bottom in an international comparison,” says Krause. The reason for this is that health insurance companies pay a fixed amount of money to hospitals for operations such as hip replacement. Thus hospitals have an incentive to buy the cheapest devices available. “Nevertheless, the reputation of the German market is high: whoever makes it here can make it anywhere,” Krause adds. International customers are looking for industrial partners with concepts that are not only economical but offer the best possible solution for patients. Amplitude’s customers are individual clinics and purchasing groups that bundle purchasing for several hospitals and according to great market power – this is a peculiarity of the German market. “Such a structure does not exist in the French home market,” says Krause.

He also keeps an eye on the evolving regulatory framework. For instance, the GBA has announced the testing of so-called quality contracts for prostheses. In future, prostheses need no longer be judged purely on cost but also by utility: for example, does the patient need fewer painkillers after surgery and are they recovering faster than with other products? All of this could play a greater role in the assessment of prostheses in future. “I am hoping that such a swing away from the pure price competition for prostheses would confirm our business strategy with high quality standards of the products,” Krause says.

In any case, the GBA’s advances underscore the fact that the search for optimum conditions in the German medical technology market continues. Companies are incentivized to push ahead with innovative developments. 
The Reinvention of the Laboratory

In many laboratories, the opportunities brought by digitization have so far hardly been exploited. Something that the “SmartLAB” network wants to change. It is looking for foreign companies to get involved in product development.

In many laboratories, digitization and automation have not yet been introduced, meaning a lot of manual work and slow processes continue, says engineer Markus Sebeck. “This slows down the work and leads to high operating costs.” In many laboratories, for each individual sample an employee must read devices and enter their results into lists or into a computer. “This often leads to mistakes,” says Sebeck. “And then you have to do all the work again.” There are also problems in research laboratories, where, for example, a lot of time is lost during the setup of experiments.

That is why members of the “SmartLAB” network are dealing with the question of how lab work could function more quickly and more economically in the future. Markus Sebeck is the project manager of the network, whose members are distributed throughout Germany. “We want to digitize and automate laboratories and make them more efficient this way,” he explains. Twelve small and medium-sized enterprises, two large companies and six research institutes are currently involved in the network. They all pool their different expertise, including laboratory operation, instruments and other equipment, measuring and testing technology, consumables, software and IT. The network is funded by the German Federal Ministry for Economic Affairs and Energy.

The members of the network not only want to collaborate on research but also to develop new products and processes. “We need labs and scientists because they know what’s going on in their labs,” explains Sebeck. “But we also need technicians and software specialists to create products that can be realized from the ideas.” Members work together in several smaller groups to develop new technologies and products. The companies then jointly decide who is going to bring the products to the market.

Sebeck is particularly keen to attract potential foreign partners, as they would give the network greater opportunities internationally. “We want to develop solutions that can be marketed in different countries,” he says.

He does not want to reveal too much about the current product slate but in the future, for example, test results are due to be automatically be sent from the measuring devices to a central computer system. In addition, the network wants to create lab equipment that self-adapts to changing user needs and assistance tools to support the user in planning, performing and evaluating tests. “Simple, fast and efficient – this is how we imagine the laboratory of the future,” he says.
At the beginning of this year, the "e-health law" came into force in Germany and will fast-track the digitization of the country’s healthcare system. The law is good news for digital health companies because it paves the way for new products, for example, in telemedicine. Health Minister Hermann Gröhe is optimistic about the industry’s future. He says, “With the e-health law, we are backing up our electronic healthcare with all our strength.”

Medical video consultations are just one example of new opportunities emerging for digital healthcare companies. The new law not only allows doctors to advise their patients via webcam, it also ensures the health insurance funds pay for the costs. About 70 per cent of the industry experts surveyed by the IT association Bitkom reported that this creates new market opportunities. For example, when patients live far away from a medical practice, or are recovering after an operation, video consultations allow them to maintain communication with their doctor. Hardware and software providers as well as IT consultants hope that this will create new revenue sources for them. Other business opportunities are also being created, as a result of the new law, with the further development of the electronic health card. Since 2015, all Germans who are members of a health insurance fund have such a card. Currently, the cards only store limited data, for example, the name of the patient, their address and patient number. From next year, additional data will be stored, including details of the patient’s blood type, allergies and emergency contacts. This additional data is to be recorded by doctors on their patients’ cards, requiring the installation of card-reading devices and the associated software in all medical practices. Pharmacies and nursery homes also need to have technology to read the cards. This provides business opportunities for software and hardware providers as well as IT consultants. “With the new law, we are paving the way for an electronic patient record,” says minister Grohe.

Parallel to the e-health law, an innovation fund has been set up to help start-up companies in healthcare to design innovative products. The fund will have an annual budget of €300m by 2019. “The innovation fund is a huge opportunity for start-ups,” says Juliane Pohl from the German medical technology industry association BVMed. Currently, 117 projects are supported by the fund, with another 228 under consideration.

**Boom for IT providers**

A new law will promote the digitization of the healthcare market in Germany, opening up many exciting new business opportunities for companies.

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