

The Medical Technology Companies

∴ ∴ ∴ ∴ **BVMed**
Enhancing Health.

Annual Report 2006/07





Medical Technologies save Lives, help heal and improve People's Quality of Life

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Anton J. Schmidt
Chairman of the Board of BVMed

Introduction

“We need a Master Plan for the Health Economy”

Medical technologies are indispensable for people's health and quality of life. They save lives. They help heal. They enable millions of patients in Germany to regain their vitality and mobility.

In recent years, major progress towards raising awareness of medical technologies among policy and decision makers in the healthcare market has been made. This includes comprehensive studies on the situation of medical technology in Germany published by the Federal Ministries of Economics and Research. Federal Health Minister Ulla Schmidt also missed no opportunity to mention the innovative capacity of our industry in the last few months. A so-called “Medical Technology Action Plan”, which is to improve the promotion of the industry's innovations, is part of the “High-Tech Strategy” adopted by the German federal government.

These initiatives and the budding strategic approach across governmental departments offer new opportunities for departing from a health policy perspective geared towards cost reduction.

What we need now is a “Health Economy Master Plan” that is aligned across all policy areas and, above all, coordinated with the government's economy, research and health departments as well as with the Federal Chancellery. As a precondition, this would require a broad discussion by society in general on how much health is worth to us. People should be openly informed that the finite resources of Statutory Health Insurance cannot deliver an unending supply of innovative healthcare benefits.

In times of limited resources there is an even greater need for more individual responsibility of the medically insured for their own health and for alternative funding concepts, so that, in the future, medical progress can continue to be made available to all patients in good time.

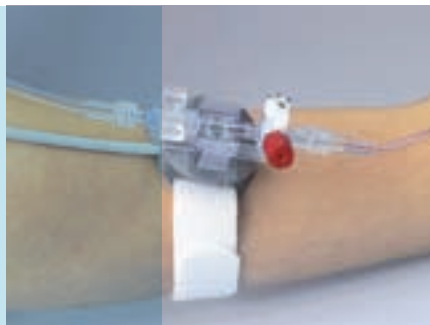
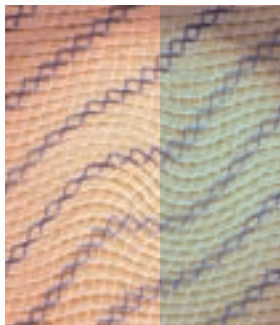
The medical technology companies are gladly prepared to actively participate in this process as a constructive and open-minded partner.

Best regards

Anton J. Schmidt
Chairman of the Board of BVMed



Small Medical Technologies with huge Impact: Brachytherapy Seeds for the Treatment of Prostate Cancer and Mesh for Abdominal Wall Reinforcement



System for Invasive Blood Pressure Monitoring



Silicone Calf Implant

BVMed's Market and Membership Development

Membership Development

Presently (in March 2007), some 206 industry and trade companies are represented by BVMed. Please find a complete list of BVMed's members on pages 22/23. In 2006, 7 companies joined BVMed. At the beginning of 2007, one further company became a member of the association. This is up against 8 withdrawals in 2006, which were mainly due to mergers and acquisitions within the industry, or insolvencies.

Market Development

In 2006, BVMed's member companies reported an increase in turnover of 4.3 percent. In 2005, turnover had increased by 2 percent, in 2004 by 1.5 percent. In the preceding years, turnover growth had been significantly stronger at 3.9 percent in 2003 and 6.5 percent in 2002.

Development in Subsectors

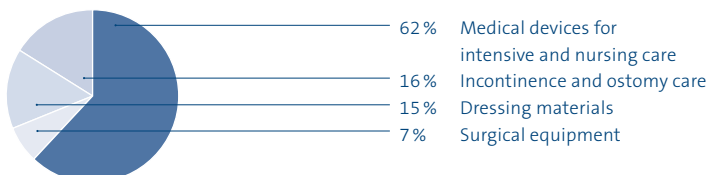
In comparison to other sectors, the category "single-use devices, intensive care medicine, nursing items" reported an above-average turnover growth of 5.6 percent. Turnover development in the sectors "single-use surgical equipment" (plus 3.4 percent), "incontinence and ostomy aids" (plus 3.0 percent) and "dressing materials" (plus 1.0 percent) was somewhat subdued. The reported rise in turnover is mainly based on volume growth. In contrast, the pressure on prices has increased even further.

Results of the Membership Survey 2006

In November 2006, BVMed conducted a comprehensive industry survey, in which 118 member companies (56 percent) participated. The most significant results are as follows:

- :: Despite the difficult economic environment, the Med-tech sector in Germany once again created more jobs in 2006. Some 46 percent of the 118 companies taking part in BVMed's annual survey state that they have created more jobs than in the previous year. In 2005, this figure was only 36 percent.
- :: In their outlook on 2007, the companies cannot yet see any silver lining on the horizon. 60 percent of the companies don't expect their economic situation to improve, while some 37 percent estimate that it will remain unchanged. 23 percent, however, fear a change for the worse.
- :: From a comprehensive healthcare reform, BVMed's member companies expect above all more individual responsibility of the patients by means of co-payment schemes (71 percent), increased freedom of choice for the medically insured (66 percent) and an outcome-oriented remuneration of healthcare services (53 percent). 43 percent advocate the concept of "basic care plus supplementary insurance" and 43 percent call for a decoupling of contributions from labor costs.
- :: As in the previous year, participants name the following as the most severe restraints on the sector's development: the mounting pressure on prices due to purchasing cooperatives (78 percent), the intricate legal framework (70 percent) as well as the continuing imposition of budgets (63 percent).
- :: Germany as an investment and industrial location for medical technology receives a fair amount of praise and appreciation from participants. Reasons named are above all the large number of well-educated and well-trained doctors (70 percent) and engineers (57 percent), the high level of patient care (65 percent) as well as the high standard in clinical research (53 percent).
- :: The low level of reimbursement in Germany as compared to other European countries is the main source of criticism.

BVMed Sales Structure





Safe Medical Devices for sensitive Procedures: Quality Check of Titanium Port and Electrode to ensure a smooth Application.

Industry Report Medtech 2006/07

Growth Market Health Economy

The health economy is one of the biggest market segments of the German economy. A total of 4.2 million people are employed in healthcare. Thus, every tenth job in Germany is based in the health economy. Despite the difficult overall economic situation, this number is still growing. 234 billion euros in total are spent on health. This represents a share of 10.6 percent of the gross domestic product, thus making healthcare an even more significant sector than, for instance, the automotive industry (9.7 percent of GDP).

Medical Technologies in Germany

Medical technologies are a significant economic and labor market factor. The medical technology companies have a considerable share in the positive development of the health economy in Germany. Healthcare spending in the medical devices sector in Germany amounted to more than 20 billion euros in 2004. This was reported by the German Federal Statistical Office in its health expenditure statistics in the fall of 2006. Of this amount, 10.1 billion euros account for medical technical aids, 9 billion euros for other medical supplies and about 1 billion euros for the sector of medical dressings, which is listed in the category "pharmaceuticals". The share of Statutory Health Insurance in the total expenditure incurred amounted to some 14 billion euros: 5.5 billion euros were spent on medical technical aids, 7.8 billion euros on other medical supplies plus the medical dressings share. Further key figures on production and export: The production of medical technology in Germany comprised some 14.8 billion euros in 2005. While foreign sales climbed by almost 17 percent to 9.2 billion euros, domestic sales stagnated. In export, Germany, with a world trade share of 14.6 percent, ranked second worldwide behind the USA (30.9 percent) but distinctly ahead of Japan (5.5 percent) (source: medical technology study of the Federal Ministry of Education and Research).

Employment Figures

The medical devices sector employs some 150,000 people in more than 11,000 companies. Of these, 1,100 companies have more than 20 employees (source: DIW Berlin, study 2005 on behalf of the Federal Research Ministry). It is assumed that the same number of jobs in

the ancillary industry depends directly on the medical devices industry. Some 6,400 people employed in the sector work in research and development.

World Market for Medical Devices

The world market for medical devices amounted to some 184 billion euros in 2004. The European market, estimated at 55 billion euros, is the second biggest market in the world, following the United States at 79 billion euros. Besides the USA and Japan, Germany is the third biggest market worldwide at 20 billion euros and by far the largest market in Europe. It is about twice as large as the French and three times as large as the Italian and the British market.

Outstanding Innovative Capability

The medical technology industry is dynamic and highly innovative. Its product cycles are considerably shorter than those in the pharmaceutical industry. More than half of the turnover is effected with products less than three years old. An average 7 percent of turnover is invested in research and development. For comparison: The share of the highly innovative chemical industry's spending on research and development amounts to 5 percent, that of the manufacturing industries to a total of 3.8 percent. According to the medical technology study of the Federal Ministry of Education and Research, the ratio of R&D expenditures to production value is twice as high in medical technology as in the manufacturing industries in general. Germany as a research location is thus of considerable importance for the medical technology companies. A further indication of the innovative capacity of the branch: According to the European Patent Office in Munich, medical technology heads the list of registered inventions with 14,700 patents. 11.4 percent of patent applications thus originate from the Medtech field, which is followed by telecommunications (10 percent) and EDP (6.7 percent). The structured employment of the ideas of users, such as doctors and nurses, for new medical technology products and procedures are of particular importance for the companies, as in 52 percent of the cases, ideas for new medical devices originate from the users.



Research, Development and Production in the Medtech Sector are subject to the highest Quality Requirements

Market Conditions for Medtech: Strengths and Weaknesses

Market Conditions – Pros and Cons

With its large number of well-educated and well-trained doctors, researchers and engineers, and the high standard of clinical research, Germany has the best prospects to bring new products and procedures to the marketing stage. Owing to our first-rate university hospitals and the numerous competence centers in medical technology, the knowledge at our command is substantial. Germany's advantages also lie in shorter approval times and in its excellent and cost-effective clinical research. The cost of bringing a new idea to marketability is at around 8 to 10 million euros on average. According to experts, these costs are considerably higher in the US at some 80 million dollars. There are, however, substantial challenges when it comes to introducing innovations into the reimbursement system so that they may then be made available to patients without delay. That is why market growth in Germany is not as dynamic as it is elsewhere.

Improved Innovation Management

The medical technology companies are sympathetic to the sickness funds, which are seeking an improved and more predictable allocation of funds in view of limited resources. If, for that reason, there is a lot of talk about "real medical progress", of "technology assessment", "cost-benefit evaluation" and "outcome research", the medical technology companies are an open-minded and constructive partner. On the other hand, the companies are also calling for consideration of the fact that an early integration of health insurance funds in the innovation process will certainly come to its limits wherever company-internal knowledge and the protection of individual ideas prior to being turned into a marketable product are concerned. Innovations are the assets of the companies in this highly competitive industry. It must be the common goal of all stakeholders to introduce innovations offering medical technological and economic progress into the healthcare system at a much faster rate. The long-term savings potentials offered by modern Medtech procedures must be taken into account in coverage decisions for medical technologies. This must be a part of the monitoring and promotion of innovations.

Value for the National Economy

The faster adoption of innovations also offers economic advantages: New examination and treatment methods lead to a reduction of sick days, shorten patients' recovery times and thus enable them to return to their social activities and their jobs more quickly. This also constitutes a benefit for the national economy as a whole. Benefit and effectiveness considerations – and thus also cost-saving potentials – of medical technologies must be put on the front burner. They must be considered an investment in people's health and productive efficiency as they establish a new understanding of healthcare through improved treatment possibilities, shorter lengths of hospital stays, lower disability rates and a reduced number of sick days. The value of innovations is from our point of view often considered for too short a term. The use of medical technology innovations in Germany is often complicated by an isolated consideration of their initial costs, which are mostly higher than those of established procedures, while failing to take into account the benefit and cost effects throughout the whole course of a treatment or disease. That is why we are calling for an "overall consideration of treatment processes".



Medical Technologies are indispensable for People's Health and Quality of Life

Promoting Medtech Innovation: What Needs to be Done?

What precisely needs to be done to utilize the potential of medical technologies as a driving force for growth? In BVMed's estimation, the dynamic change of medical possibilities and services must now be followed by a change of the healthcare system that is just as dynamic.

- :: We need a **new health economy** with more competitive elements, increased freedom of choice and more individual responsibility of patients for their own health. Our vision is a new health economy in which everyone is free to "buy" their own individual health insurance coverage. Accordingly, this would include the provision of basic care as well as voluntary supplementary insurance options – with premiums emphasizing prevention or with deductible rates, with or without free choice of doctor, a range of alternative options in specific fields of healthcare, etc. This adds up to more individual responsibility. This would be a system with a great number of competitive elements – and most assuredly also with favorable effects on Germany as a business location.
- :: We need the clear will to introduce **innovations** into the German healthcare system and to establish processes for their timely adoption. For this purpose, we suggest the establishment of a cross-departmental "Medical Technology Task Force".
- :: Many innovations are initially applied in hospitals. Medical technological innovations in hospitals are subject to reimbursement by Statutory Health Insurance, unless there has been a negative decision of the Joint Federal Committee (JFC – Gemeinsamer Bundesausschuss). This principle of "**permission with the reservation of prohibition**" in the inpatient sector must be adhered to, so that innovative medical technologies can be made available to all patients who require them without delay.
- :: The Medtech companies are still insufficiently involved in the proceedings of the JFC and a **more active industry participation** is called for. As a first step, BVMed has suggested a case-related designation of medical expert participants from industry in the committee's relevant key deliberations.

:: The introduction of innovations into the system must not be impeded by too restrictive requirements for the provision of **evidence**. While randomized controlled clinical trials are considered "gold standard" for medical devices, they are not ethical or even necessary in every case. Lower evidence levels can also provide the data necessary for demonstrating a technology's real benefit. The required evidence level should be adapted to the technology and disease in question.

:: We must **optimize** the general conditions for **research and development** through improved research management. This requires the establishment of a network of companies, users and scientific research, particularly in the fields of bio, micro and nano technology. We plead for regional clusters including medical technology companies, research institutes and educational establishments, manufacturers of important preliminary products up to software as well as suppliers of venture capital.

:: Above all, there is a need for **more outcome research**. Basic and interdisciplinary research, by means of which medical and healthcare as well as their general conditions are causally defined and further developed, must in the future play a more crucial role in the healthcare system. From the industry and trade companies' perspective, more outcome research is needed to reflect the overall cost of a therapy and thus be able to demonstrate its individual long-term advantages for patients and the national economy.

:: We need **legal clarification** on the necessary and politically aspired cooperation of industry, hospitals and physicians. The challenge in this cooperation is the differentiation of legitimate sponsoring and corruption in individual cases. Here, the legislators are called upon to draw a clearer line than before. Meanwhile, industry seeks to establish joint solutions in the market by means of model contracts between companies and hospitals or their doctors, respectively. In 2006, a corresponding guideline providing model contract texts was published by BVMed and the Association of Hospital Directors (VKD) in a joint effort.



Ready for Emergencies: First-Aid Bag, Emergency Suit, Special Cannulas for atraumatic Insertion

Health Policy

Development of SHI Finance

The financial situation of Statutory Health Insurance (SHI) developed more positively than expected. According to estimates of the Federal Ministry of Health, the sickness funds will close 2006 with a surplus of some 1 billion euros. However, there was still need for legislative action – due to the final payment of a substantial tax subsidy of 4.2 billion euros to the SHI and the in part substantial debts of the health insurance funds.

Healthcare Reform/SHI Competition Strengthening Law (WSG)

The year 2006 was characterized by the political negotiations on the German healthcare reform. Owing to the strongly contradictory interests of Christian Union and Social Democrats in the Grand Coalition, the directional conflict between citizens insurance and healthcare premium remained unsolved. The federal government was unable to develop a suitable concept for securing a sustained income for Statutory Health Insurance. The SHI Competition Strengthening Law (Wettbewerbsstärkungsgesetz – WSG) is marked by a multitude of new regulations and short-term cost-cutting measures, such as obligatory tenders in the medical technical aids sector or the hospital emergency levy in favor of the health insurance funds.

BVMed's Activities in Health Policy

With a newly formed department, BVMed has intensified its health political efforts and contacts since August 2006. BVMed held a variety of talks with almost all members of the parliamentary health committee and with representatives of the parliamentary parties, the federal states and the ministries. In addition, BVMed organized parliamentary breakfasts and dinner talks with members of the German parliament. Decision-makers from research, business and technology were also included in BVMed's activities. Despite the predomination of the public debate with issues such as the so-called "health pool", private health insurance and the restructuring of the sickness funds, BVMed was able to raise policy-makers' awareness of the concerns of the medical technical aids sector. Supportive measures such as statements, press conferences and background talks, an information flyer campaign and newspaper adver-

tisements contributed to a deeper understanding of the Medtech aids sector. Thus, a more precise stipulation of exceptions from obligatory tenders could be achieved. Accordingly, custom-built technical aids and aids marked by a high service ratio are exempt from the tenders. The care with technical aids is to continue to be provided close to patients' homes and with assured product and service quality.

BVMed had warned at an early stage that the planned reorganization contribution in the hospital sector might lead to a decreased quality in care for patients with medical devices at the expense of medical-technological progress. If this comes to pass, patients can no longer be provided with the innovative medical technologies they need in due time. In the course of the legislative proceedings, a reduction by half of the contribution amount of 500 million euros – and thus a mitigation of the situation – was accomplished. BVMed continues to advocate a more active participation of the Medtech industry in the proceedings of the Joint Federal Committee (JFC) by means of a case-related designation of medical expert participants from industry in the relevant key deliberations. It is of the utmost importance that the principle of "permission with the reservation of prohibition" in the inpatient sector remains in place.

Range of Health Policy Services

BVMed is closely monitoring the current legislative projects and provides its members with various new services, such as the weekly "health policy chart pool". BVMed's new newsletter "Health Policy in Depth" offers detailed health political information. This range of new services is topped off by a "Health Policy Monitoring" service on BVMed's extranet pages, which provides interested members with rapid access to relevant documents and schedules of current legislation.



Medical Devices typically used in Hospitals: Sutures, Suction Devices, System for Oxygen Measurement, Surgical Drapes and High-Barrier Gowns, Larynx Mask

G-DRGs in the Hospital Sector

The Second Year in the Convergence Phase, 2006: Mounting Pressure on Industry

With the conversion to the DRG system, hospitals have come under increasing economic pressure. As a result, the procurement of consumer goods such as medical devices is more and more shifted from medical personnel to procurement departments. This leads to further price pressure and need for adjustment. Excessive pressure on prices, however, deprives the companies of their innovation potential. At the same time, the hospitals are affected by the dropping procurement costs themselves, as – with a delay of two years – the price erosion is reflected in the DRGs. The DRGs are compelling the hospitals to improve their internal process management to adapt to the new system. Medical technology companies will need to address questions on the overall cost of care per patient case, rather than merely the cost of their products alone. New medical technology procedures must help optimize processes, heal patients at a faster rate and thus shorten their lengths of stay.

G-DRGs 2007 and the Future of Hospital Financing

The new DRG catalog for 2007 comprises 1,082 DRGs and 105 supplementary payments. The new catalog results from the calculation of 225 hospitals which provided data of 2.4 million hospital treatment cases. As in the previous years, BVMed was actively involved in the proposal process for the further development of the DRG system. New examination and treatment methods (Neue Untersuchungs- und Behandlungsmethoden – NUB), among them innovative medical technologies, have been integrated into supplementary payments for the first time. The DRG Institute InEK learned from the calculation data of 2005 that the drop in unit prices of active implants and other medical devices is one of the main reasons for changing DRG prices.

Need for Adaptation of the DRG Innovation Clause

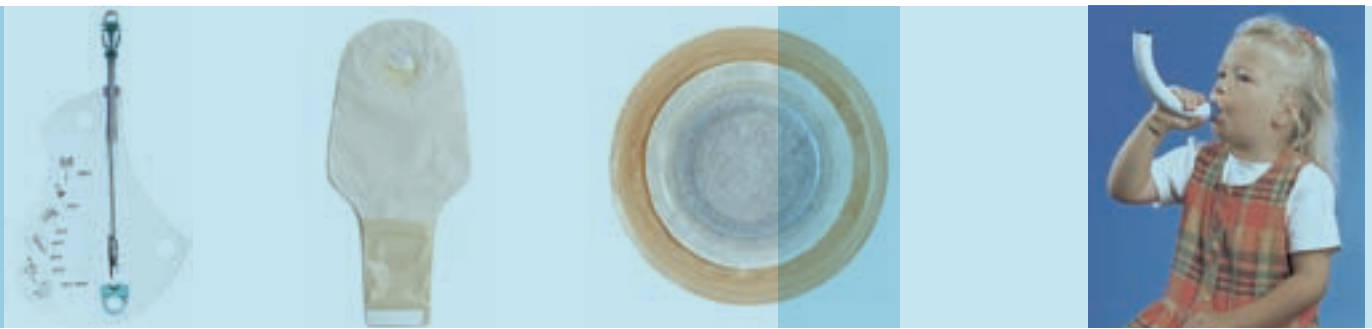
A study conducted last year on behalf of BVMed by the Institute of Health Economics (Institut für Gesundheitsökonomie – IFG) under the direction of Professor Dr. Günter Neubauer examined the application of the

so-called innovation clause on medical technologies and its implementation by the hospitals. The study was to analyze the NUB process for the evaluation of new examination and treatment methods and identify practical need for improvement. Among the demands stipulated in the study is the possibility of filing applications during the year. The hospitals, too, advocate that an innovation that has already been rated as status 1 by the InEK keep this status until the innovation is implemented in the DRG system, so that they are no longer obliged to file a new application every year. Furthermore, negotiated innovation clause payments for new treatment methods should have validity for all hospitals with the same medical care level all over the country. Verifiably innovative hospitals should also be provided with an “innovation pool” for refinancing.

Study on the Development of Hospital Service Utilization until 2010

In a further study, BVMed commissioned the German Hospital Institute (DKI) with a differentiated analysis of the development of hospital service utilization in the next few years until 2010, from which possible changes in the demand for the medical services of hospitals could be inferred. The study came to the conclusion that the number of inpatient treatment cases will rise only insignificantly in the forecasting horizon. Irrespective of a rather moderate change in the total number of cases, considerable diagnosis- and age-related changes are to be expected. A further result: Medical technologies are by no means the “cost drivers” in German hospitals as is often alleged. The percentage increase in the demand for medical services per patient was lower than the rise in GDP per capita in the past. Medical technology innovations will continue to generate growth in the healthcare system that will approximate the growth rates of the Gross Domestic Product.

To the hospitals, the financing of medical progress poses an ever increasing challenge. This stems from the rigid connection of hospital budgets to changes in the revenue base. The expected cost increases in the medical service demands of hospitals cannot be compensated by cuts in other areas. Thus, additional financial means for the financing of medical progress are called for.



Technical Aids are also Medical Devices: Single-Use Urinary Catheter for Incontinence; Ostomy Bag with special Filter, Products for Respiratory Therapy

Technical Aids

Drop in Expenditures in Technical Aids Sector

The Medtech aids sector has been subject to fierce competition for a long time. However, the development of expenditures in this sector clearly shows that it “works” in the current system. Accordingly, expenditures on technical aids and their share in the total expenditures of Statutory Health Insurance – despite the ever-ageing population and the resulting rise in demand for medical care – decreased even further in 2006. The extension of the reference price system, the boosting of contract competition and the restrictive pricing policy of the health insurance funds leave their marks on the technical aids industry. The effects hit the manufacturers and the providers of care with technical aids to the same extent. All in all, the Medtech aids sector recorded a drop in expenditures of about one percent. In detail, this amounted to the following figures in the first three quarters of 2006: In the first nine months of 2006, 3.257 billion euros were spent on technical aids (West 2.677 billion euros and East 580 million euros), representing only a scant three percent of the total SHI expenditures. In the first nine months of the previous year, technical aids’ share in expenditures had still amounted to 3.1 percent. Compared to 2005, the share of Medtech aids in total expenditures has thus decreased even further.

Federal Reference Prices

Two years after the first federal reference prices for the categories arch supports, technical aids for compression therapy, visual and hearing aids, as well as absorbing incontinence aids were stipulated, reference prices for the category draining incontinence aids have been introduced as well, and have come into effect on January 1, 2007. BVMed’s expert statements on the update of product group 15 (PG 15) of the medical technical aids register and the assignment of reference prices for draining incontinence care as well as continuous talks with all parties concerned contributed to the grouping of incontinence products according to similarity and equal value in function. Furthermore, detailed market analyses conducted by BVMed in the incontinence and ostomy sectors enabled the National Associations of SHI funds to perform a weighted calculation of reference prices. Thus, the market conditions are more realistically reflected. On the whole, an increase of prices in several

reference price groups both in incontinence and in ostomy care was achieved, so that basically, a dramatic cut in the quality of patient care is not to be expected. Furthermore, an early and continuous exchange of ideas with the health insurance funds’ associations resulted in a raise of all reference price groups by the increase in value added tax as of January 1, 2007.

Current Developments in the Technical Aids Sector

With the upcoming healthcare reform, the SHI Competition Strengthening Law, the lawmakers bank on stronger price and quality competition in the technical aids sector. In order to consequently implement this and prevent pure price competition, the focus must be on the care and quality aspects in contracts, tenders, or reference prices. This presupposes the development and establishment of nationally uniform quality standards. Together with the SHI funds’ medical review board and national associations and the “Quality Network for Technical Aids”, BVMed is actively involved in the timely development of quality guidelines, among others for ostomy, incontinence and tracheostomy care as well as for anti-decubitus aids. In September 2006, the Federal Social Court confirmed the ruling of the Higher Social Court of Northrhine Westphalia on the requirements on the demonstration of evidence with regard to the adoption of technical aids into the medical technical aids register (judgment of the Federal Social Court, reference number: B 3 KR 28/05 R of September 28, 2006). Consequently, a product’s performance and safety are categorically covered by CE marking, which has already been taken into account in the new healthcare reform law. Thus, BVMed’s demand of many years that overlapping assessments of technical aids should be prevented and additional evidence should only be requested in areas exceeding the requirements of CE marking, e. g. for “medical benefit”, has been fulfilled.



Patient Mobility provided by Medical Technologies: Peritoneal Dialysis (left) and Infusion Pumps (middle and right)

Homecare

Growth Market of the Future

Homecare is still considered a most promising growth market. An increasing number of people depends on therapy models provided in their own homes, which is particularly due to demographic changes and multi-morbidity in old age. On the other side of the equation, however, is the cost pressure in Statutory Health Insurance. Almost all homecare services include the provision of patients with technical aids. In 2006, patient care with technical aids was in the focus of policymakers' demands for cost savings in Statutory Health Insurance. Thus, the blueprint of the draft on the healthcare reform stipulated that Statutory Health Insurance was to effect savings amounting to 300 million euros in the area of medical technical aids. However, the cost pressure in health insurance must not lead to a relocation of services into long-term care insurance. In the context of the healthcare reform, lawmakers have acted on the debate on the differentiation between the duties of health and long-term care insurance in the shape of a legal clarification on § 33 of Book Five of the German Social Code (SGB V).

Positioning of Homecare

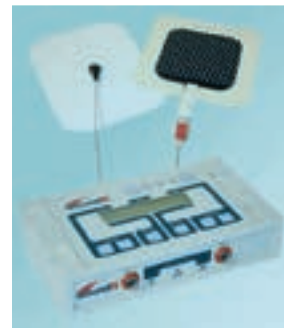
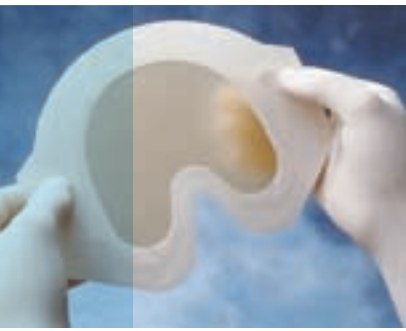
As the term "homecare" is occupied by the most diverse care providers in the healthcare system, a clear positioning of the homecare companies is vital. The health insurance funds continue to affect the competition among homecare companies by focusing on the price rather than on quality. On top of unilaterally imposed contractual terms, companies are facing an increasing amount of duties in terms of administration and documentation, which leaves them with a drastically reduced leeway for rendering on-site services based on the patient's individual needs. The healthcare reform poses a further challenge to the providers of homecare. Tenders are to be the instrument of choice for the determination of contracts by health insurance funds. However, there are still ambiguities in the interpretation of the planned legal provisions on tenders. The rationale on the new § 127 SGB V stipulates that public procurement law is to apply to tenders for care with technical aids. It is still unclear how the health insurance funds will put the new provisions into practice. Possibly, the homecare companies might even have to adapt individually to each sickness fund's interpretation.

Electronic Health Card

The introduction of the electronic health card and the so-called e-prescription is a topic of some significance to the homecare companies. As homecare comprises care involving drugs, dressings and technical aids, homecare providers must receive access to electronic prescriptions from the very start in order to rule out competitive distortions with other care providers, and pharmacies in particular. In the pilot phase, e-prescriptions are limited to drugs subject to sale by pharmacists only. In the long term, all prescriptions are to be transmitted electronically. Until then it must be ensured that all care providers are connected to the telematics infrastructure and that the electronic health card takes into account the particularities in the homecare sector.

New Models of Care

In the estimation of the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung – KBV), medical healthcare centers are the healthcare organization of the future. According to the association, the most important operators of medical healthcare centers are SHI physicians with a share of 68.6 percent and hospitals with 28.1 percent. There has also been a further dynamic increase in integrated care contracts. Even although there is room for doubt on whether the concepts in many of the contracts concluded stand for true structural improvements, the race for the signing of contracts has not abated. This is also evident in recent case law developments, according to which so-called "general practitioner contracts" which have been concluded as integrated care contracts are being challenged. The period of start-up funding for integrated care has been extended to 2008. It would be sensible to channel the available funds to those contracts truly implementing intersectoral care concepts that bring about noticeable improvement in the patients' quality of life.



Wounds need proper Care: Various Wound Dressings

Electrostimulation System for the Treatment of Wounds

Systems for the Prevention of Pressure Ulcers

Medical Device Legislation

Developments in European Legislation

At European level, a new legislative act aiming at the legal alignment of 23 harmonization directives remains in development (“New Approach Review”). The question of whether the existing directives on active implantable medical devices and other medical devices should be changed into EU “regulations”, which would be directly applicable in the EU member states without transposition into national law, was also under discussion. In that case, however, the area of “market surveillance” would remain under sovereignty of the EU member states and could not be the object of an EU regulation. The most significant proposals for amendment pertain to conformity assessment, the requirements on clinical evaluation, post-market surveillance, the compliance of custom-made devices with the requirements as well as the alignment of the directive on in-vitro diagnostic devices. On top of that, the health committee of the European Parliament demands the following: All medical devices intended for single use must be examined for technical reusability by the manufacturer. If a manufacturer places single-use devices on the market, he must give reasons for ruling out multiple use. The European Council, which is under German presidency in the first six months of 2007, is trying to persuade the European Parliament to agree to a compromise solution, as the risks of uncontrolled reuse of single-use medical devices are grave.

EU Regulation on Advanced Therapies

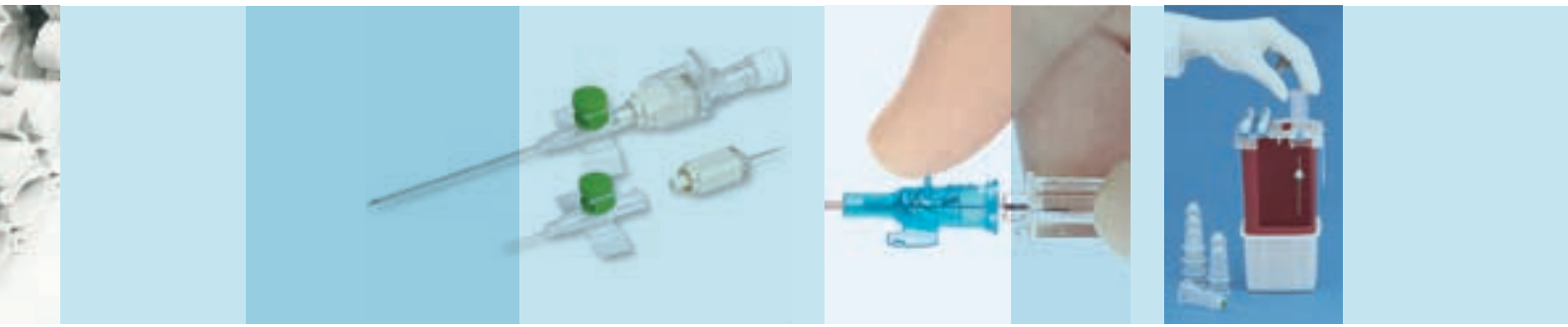
A further focus of activities at European level is a proposal for a regulation according to which tissue-engineered products would be regulated under the EU pharmaceutical legislation and which seeks to standardize the application of law. It is not yet clear, how far medical devices, particularly combinations, will be affected. A special committee, the Committee for Advanced Therapies (CAT), will be created at the European agency EMEA to assist in the evaluation of combined products.

Third Amendment to the Medical Devices Act (MPG)

The cabinet draft on the “Law on the Amendment of legal and other Regulations relating to Medical Devices” of December 13, 2006 will come into effect on July 1, 2007 and serves the purpose of amending the Medical Devices Act, the AMG (Medicinal Products Act, or Drug Law), the MPSV (Medical Devices Safety Plan Ordinance), the DIMDI ordinance and SGB V (Book Five of the German Social Code). The planned amendment of § 31 SGB V, which governs the remuneration of medicinal product-like medical devices, has led to insecurities among the manufacturers. The terms “substances” and “preparations of substances” used in the amendment are not clearly defined in German law. It is debatable as to whether objective medical devices containing medicinal products can be “substances” at all. The legislators are called upon to provide legal clarity on this issue. The amendment fails to provide the requested redefinition of “operators”, which would include the health insurance funds. The health insurance funds allege, without substantiating their claim, that the healthcare system would suffer a cost increase of 2 billion euros if the operator regulations also applied to sickness funds which are operating medical devices. For the patients, this position means the creation of an unpleasant two-class safety, depending on who is the operator of the device that is used. As far as the new amendment to the Medical Devices Ordinance (MPV) serves the national transposition of the EC Directive on the reclassification of certain joint implants, it will come into effect on September 1, 2007.

DAMA Establishment Act

The “Act on the Establishment of a German Drugs and Medical Devices Agency (DAMA)” is scheduled to come into force on July 1, 2007. The Establishment of a German Drugs and Medical Devices Agency DAMA and its new Federal Office for Medical Devices (previously department 9 “Medical Devices”) is aimed at increasing the efficiency of the present Federal Institute for Drugs and Medical Devices (BfArM). However, the draft does not change the jurisdiction of the BfArM for medical devices.



Prevention of Sharps Injuries by Use of Safety Products

Patient and User Safety/Environmental Issues

Reuse of Medical Devices

Despite being labeled as “single use only”, single-use medical devices are reprocessed and reused on other patients in numerous cases. Reprocessors often justify this practice on the basis of economic and environmental benefits. These perceived benefits are, however, questionable and of secondary importance. The primary concern in the manufacture, operation and application of medical devices is the health and safety of patients. This is required by the Medical Devices Act. For this reason, manufacturers advocate that the exposure of patients to unnecessary risk by the reprocessing of single-use devices contrary to their designated use is eliminated. These high-performance, filigree devices are often highly sensitive, so that their reprocessing must not only be ruled out for reasons of hygiene but simply because they become unusable after their first use. BVMed has been directing the attention of users and operators to this problem for many years. Still, patients are put at risk by defective reprocessed single-use devices. The presentation of a patient story and damaged devices in a TV magazine in 2006 provided for a heated discussion.

Reprocessors have come forward with a proposal according to which the German regulatory framework should serve as a model and there should be a detailed, risk-based stipulation of quality requirements for reprocessing – as laid down in the joint recommendation of the Robert Koch Institute and the German Institute for Drugs and Medical Devices, the so-called “Hygiene Requirements for the Processing of Medical Devices”. The manufacturers of single-use medical devices are calling for a prohibition of this practice, as is the case in other EU countries. The Third Amendment to the Medical Devices Act, which is to come into force in 2007, will not improve legal clarity on this issue. Regrettably, the amendment to the Medical Devices Operator Ordinance fails to provide legal clarity on the obligations of operators and thus to ensure a more binding protection of patients. The announced revised wording on the function of operators of medical devices, according to which health insurance funds and providers of medical supplies would have qualified as operators as well and would thus have been obligated to ensure a high quality level in the reprocessing of medical devices, was omitted.

Prevention of Sharps Injuries: TRBA 250

The number of cuts, puncture wounds and scrapes sustained by healthcare employees in Germany is estimated at an annual 500,000 cases. Injuries with pointed or sharp instruments pose one of the greatest risks of contracting hepatitis infections and HIV. Therefore, the “Technical Guideline for Biological Working Materials” (TRBA 250), originally issued in 2003, was revised and the new version came into effect on August 1, 2006. According to the guideline, the use of safety devices in medical care for specific patient groups as well as in emergency care, emergency rooms and in prison hospitals, is mandatory. On the other hand, the individual assessment of risk potential and thus also the decision to forgo the use of safety devices – even in high-risk areas – is largely left to the operators of medical facilities. For this reason, BVMed organized a workshop for representatives of medical facilities, the relevant accident insurance companies and authorities in order to demonstrate the most suitable ways of implementing the technical guideline TRBA 250.

Environmental Legislation: REACH

The most significant environmental issue was the European Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals, in short: “REACH”. The comprehensive regulatory framework for the reorganization of the European legislation on chemicals will come into force on June 1, 2007 and will entail a vast number of obligations, particularly for manufacturers and importers of substances and preparations, but also for manufacturers of articles and downstream users. Therefore, medical technology companies are basically also affected by the policy, even despite the fact that safety of human health is already regulated by the legislation on medical devices. For this reason, the associations at European level and BVMed had advocated an exemption for medical devices, which was, however, ultimately only achieved in parts through an exemption of medical technologies from some of the requirements of REACH. In a joint workshop with the diagnostics industry, the extent to which the medical technology companies will be affected will be fathomed.



7th Press Seminar in Berlin



Two-day Medtech Communications Congress with information booths and workshops



Shooting of Nano Medicine Film for TV Service Medical Technology

Communications/Press

The future-oriented growth market of medical technologies is attracting increasing attention from the public – and thus from the trade and daily press. Yellow press publications are rapidly gaining in importance as a target group of the medical technology companies' communication strategies, as everyone is interested in health topics. This poses considerable challenges to the communications work of the Medtech industry. Successful communication must be recognized as a strategic priority at management level. BVMed offers its support to all stakeholders by holding its annual Medtech Communications Congress. 2007's congress will take place in Cologne on June 5 and 6, 2007.

TV Service Medical Technology

The objective of BVMed's "TV Service Medical Technology" at www.tvservice.bvmed.de is to improve the positioning of new medical technology procedures in television. BVMed's TV service provides professional footage including interviews, which may be used by TV broadcasting companies free of charge. Next to footage, complete films on innovative medical technology therapies – presented via patient stories – can be downloaded from the internet or ordered on DVD. This is of particular interest to teachers or other information disseminators. The films and footage are available free of charge for all interested parties. In addition, there are also radio contributions on various medical technologies. Meanwhile, there are films and radio contributions on twelve areas of medical technology – the most recent ones covering nano technologies, intestinal diagnosis and obesity surgery. Numerous films and contributions have already been broadcast on various news and local channels. Thus, the film "pacemaker medical technology" reached some 3.5 million viewers in 19 timeslots.

PR Campaign "Aktion Meditech"

The PR campaign "Aktion Meditech", initiated by BVMed and AdvaMed, involves doctors and patients, individuals, groups, companies and associations. The campaign has made it its business to inform on new treatment methods in medical technology and to ensure that affected patients get a chance to participate in healthcare policy. With its intensive media work in 2006,

Aktion Meditech reached 85 million readers via 150 articles in yellow press magazines. Further activities consisted of an annual patient group symposium, media seminars, four so-called "Berlin Talks" for policy makers and representatives of hospitals and sickness funds, as well as a quarterly newsletter. All issues and information can be found on the internet at www.aktion-meditech.de.

Media Work and Image Cultivation

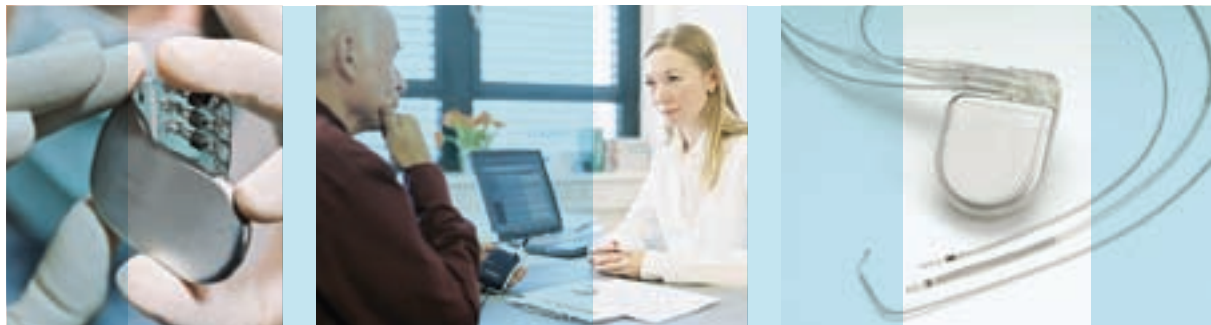
While Aktion Meditech continues to attract a lot of yellow press attention, BVMed's media work concentrates on the trade, daily and economic press. 2006's media tools were, among others, press releases, press conferences, articles and contributions for magazines as well as media cooperations. 17 million reader contacts were achieved with more than 550 articles. The continuous supply of information is supplemented by weekly newsletters and an e-mail service presenting up-to-date news as well as by press releases and monthly BVMed reports in English. For the positive promotion of the medical technology sector's image BVMed carried out further projects, such as its own booth at the Capital Congress in Berlin in May or the seventh BVMed press seminar in November 2006.

Internet and Extranet

In 2006, BVMed's German and English internet pages at www.bvmed.de recorded some 19 million hits in total. A total of 900,000 individual visitors accessed the association's websites, which stands for an increase of some 43 percent over the previous year (630,000 individual visitors). In addition, there are further, separately logged internet presences such as the new TV Service Medical technology at www.tv-service.bvmed.de, which provides professional films and footage on innovative medical technologies. BVMed's extranet offers a central information and communication platform for all member companies.

9th E-Commerce Conference

With its so far 9th E-Commerce conference in February 2007 on electronic procurement, BVMed established an "E-Procurement get-together" and an information and communication platform for hospitals, manufacturers and service providers.



Help for the Heart: Three-Chamber Pacemaker with Home-Monitoring Technology, Pacemaker for Cardiac Resynchronization Therapy

Reports from BVMed's Expert Committees

In more than 50 focus groups, sectoral interest groups and working groups, BVMed offers its members a platform for constructive dialog and exchange of views, thus leading to a unified position on matters of common interest.

Focus groups address topics of general concern to all members, irrespective of their particular products, on a continuous basis.

Sectoral interest groups consist of members working in a specific market or product area, who desire an additional representation of their particular specialist interests.

Working groups and sub-groups are committees set up on a temporary basis to deal with specific subjects, providing expert support to the BVMed board and the management team.

Focus Groups

Focus Group "Healthcare Systems" (AKGS)

AKGS prepared a statement on the evaluation methods paper of the Institute for Quality and Economic Efficiency in Healthcare (IQWiG). Furthermore, AKGS is actively involved in the work of the German Institute of Medical Documentation and Information's HTA Board of Trustees relating to medical devices. The DRG guide "Introduction of innovative medical technologies into the G-DRG system" was revised. The group devised the concept of BVMed's innovations forum and continued its successful cooperation with the Institute for Health and Social Research (IGES), the sickness fund TK (Techniker Krankenkasse) and the BKK Bundesverband in the shape of a joint congress on innovation.

Focus Group "Legal Issues" (AKR)

AKR holds joint meetings with the members of the "Network Medical Devices", a group of eleven specialized lawyers. AKR is in charge of updating and editing BVMed's "WiKo-Commentary on Medical Device Legislation" and its case-law overview on CD-Rom featuring some 200 court rulings on medical devices. In May 2006, the group organized the second annual BVMed symposium on "current legal issues pertaining to medical devices" and an information event on anti-corruption legislation.

Focus Group

"Regulatory and Public Affairs" (AKRP)

Among the key issues addressed by AKRP in 2006 were the requirements on the labeling, certification and clinical evaluation of medical devices, the relation of the Medical Devices Act to radiation protection law, market surveillance and regulations for medical devices in non-EU countries. AKRP is also actively taking part in the updating of BVMed's publications on medical device legislation. Further issues are the active participation in standardization projects, the monitoring of legislative projects as well as the exchange of information and views with the relevant federal and state authorities, the national fellow associations and the German Institute for Standardization (DIN).

Focus Group "Environment" (AKU)

Three AKU sub-groups addressed the three environmental issues of the highest significance to BVMed's member companies: the new EU Chemicals Policy REACH, the amendment to the German Packaging Ordinance and the Electric and Electronic Devices Act. In February 2006, the sub-group "AG REACH" began its assessment of the direct impact of REACH on the medical technology companies. These analyses will be concluded in a workshop for BVMed's member companies in April 2007. On the basis of a first draft of the Fifth Amendment to the German Packaging Ordinance, the responsible sub-group prepared proposals and questions which were submitted to the Federal Environment Ministry.

Focus Group

"Electronic Communication" (AKEKOM)

This group acts as a source of information on the automated labeling of devices by means of "Auto-ID systems", which are, basically, linear or two-dimensional bar codes. The evaluation of the possible advantages of radio frequency identification (RFID) labels is steadily gaining in importance. The HIBC and GS1 (EAN) systems remain the most significant Auto-ID solutions for medical devices. Particularly remarkable was the rapid development of the GS1 "Healthcare User Group" (HUG), an initiative of companies from the medical devices and pharmaceutical industry which advocates the implementation of bar code solutions in various sub-groups.

Focus Groups

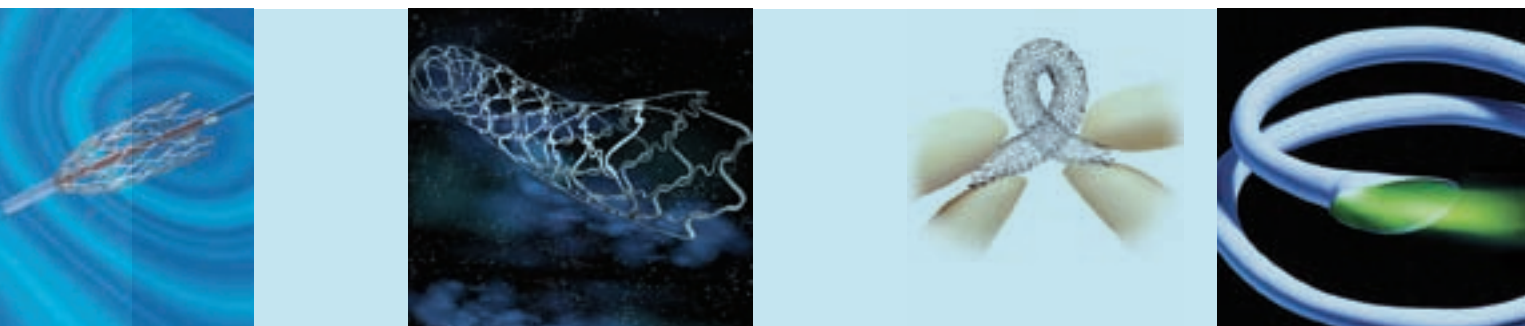
Healthcare Systems (AKGS)

Legal Issues (AKR)

Regulatory and Public Affairs (AKRP)

Environment (AKU)

Electronic Communication (AKEKOM)



Help for the Blood Vessels: Stent Technologies and Vascular Prostheses for various Areas of Application

Sectoral Interest Groups

- Bandages (FBB)
- Blood (FB Blood)
- Brachytherapy (FBBT)
- First Aid Materials (FBEH)
- Ethylene Oxide Sterilization (FBEO)
- Trade/Homecare (FB HH)
- Anti-Decubitus Aids (FBHD)
- Homecare (FBHC)
- Infusion Therapy (FBIV)
- Intraocular Lenses (FBIOL)
- Cardiac Medical Devices (FBKMP)
- Compression Stockings (FBKS)
- Artificial Feeding (FBKE)
- Health Insurance Law for Care Providers (FBLL)
- Mechanical Thrombosis Prophylaxis (FBMT)
- ...

Sectoral Interest Groups

Sectoral Interest Group “Blood” (FB Blood)

The members of this group are manufacturers of blood bags and devices for apheresis. Following a series of discussions with the German Federal Institute for Drugs and Medical Devices (BfArM), the members of FB Blood prepared a product matrix providing users with an outline of the plastic materials their products are made from. The matrix was published on BVMed’s website and will be gradually updated with further overviews.

Sectoral Interest Group “Brachytherapy” (FBBT)

FBBT’s working group “Interstitial Brachytherapy” (PG IBT, Seed method) promotes the admission of this form of therapy into the reimbursement catalog for office-based outpatient care (Einheitlicher Bewertungsmaßstab – EBM). The method is currently under evaluation by the Institute for Quality and Economic Efficiency in Healthcare (IQWiG) on behalf of the Joint Federal Committee. Members of the working group actively participated in the hearings on the preliminary report.

Sectoral Interest Group “First-Aid Materials” (FBEH)

FBEH represents the interests of the manufacturers of first aid kits for cars and working areas. The adaptation of the contents of first aid kits according to the latest findings in emergency medicine and the harmonization of requirements in the relevant standardization work were the central aims of this group. FBEH’s working group “Communication” (AGK) continued its well-established press mailings, promoting the practical applications of car first aid kits in newspapers, magazines and online media.

Sectoral Interest Group “Trade/Homecare” (FBHH)

In order to accommodate the particular interests of the trade companies represented by BVMed more adequately, a separate platform for political opinion-forming and exchange of ideas among the affected trade companies was established. The aim of this platform is to identify synergies between the industry

and trade companies and utilize them to a greater degree. The group determined strategic health political positions of the trade companies and carried out various high-publicity measures. The most recent project, for instance, was the development of a half-page advertisement, which was published in the Sunday editions of the two major dailies Bild and Frankfurter Allgemeine Zeitung.

Sectoral Interest Group “Homecare” (FBHC)

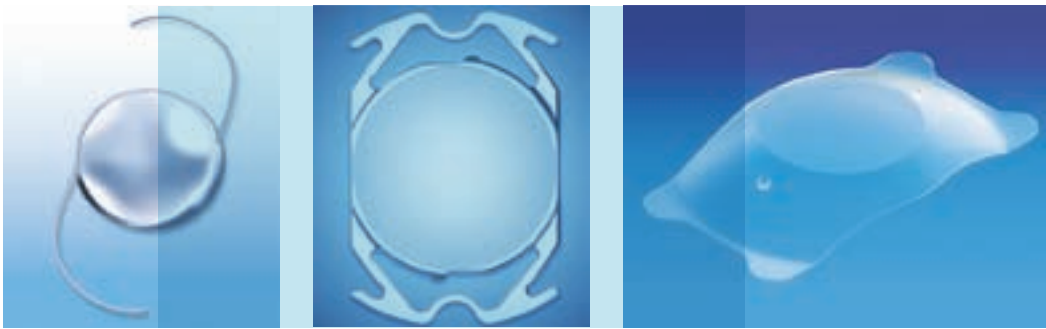
FBHC compiles information on new forms of care and supports the European umbrella association EUCOMED in its work. On account of the increasing overlapping and occupation of the term “homecare” from the nursing and medical technology perspectives, FBHC initiated a joint working group with bpa, the German association of providers of social services. The objective of this group is to reduce misunderstandings among sickness funds and politicians by means of shared terminology. For this purpose, the group is preparing a “homecare” guideline. In cooperation with representatives of the German Association for Medical Rehabilitation (DEGEMED), a sub-group of FBHC compiled a general agreement on structured transfer management of medical care, which can be entered into by all interested member companies on both sides.

Sectoral Interest Group “Infusion Therapy” (FBIV)

This sectoral interest group prepared a proposal for the restructuring of product group 03 of the medical technical aids register based on the particular areas of care (parenteral feeding, chemo therapy, pain therapy, etc.). The proposal was presented to the federal association of guild health insurance funds.

Sectoral Interest Group “Intraocular Lenses” (FBIOL)

The central issue of the companies represented in FBIOL remains the question of how a provision of patient care that is both of high quality and affordable can be ensured. This is countered by the current trend in the SHI reimbursement system, where at times even the financing of required cataract procedures is denied to patients as soon as they opt for special lenses that would, for instance,



Help for the Eyes: Intraocular Lenses, implantable Contact Lenses, Measurement of Intraocular Pressure

also be suitable for correcting their vision. A new reimbursement model for intraocular lenses which – along the lines of BVMed’s “Delta Financing Model” – would provide patients with the option of settling the balance remaining after reimbursement of a basic remuneration by Statutory Health Insurance by way of private contributions, is designed to live up to the requirements of securing an individual care of patients, containing the sickness funds’ material cost expenditures and providing for timely market access of innovative products and devices. FBIOL will increase its efforts in the promotion of this model.

Sectoral Interest Group “Cardiac Medical Devices” (FBKMP)

FBKMP promotes medical technologies and devices used in the cardiovascular system, including, among others, stent and catheter systems, heart valves, active implants such as pacemakers and implantable defibrillators, as well as heart-lung machines. Owing to their high innovation potential, a timely and appropriate adoption of these technologies in the reimbursement catalogs is an ongoing concern. For this purpose, the group maintained intensive contacts to the relevant medical expert societies and professional associations.

Sectoral Interest Group “Artificial Feeding” (FBKE)

The discussion on the revision of the pharmaceutical guideline on the reimbursement of oral supplement and tube feeding represented the main focus of this sectoral interest group. The amendments brought about by the Federal Ministry of Health’s executive fiat were actively monitored. A further key issue was the revision of the quality standards for enteral feeding. As the quality of services is to be reflected in the medical technical aids register to a greater extent, these standards are once more in need of amendment.

Sectoral Interest Group “Health Insurance Law for Care Providers” (FBLL)

FBLL addresses the current questions of member companies relating to the provision and reimbursement of healthcare services within the legal framework of interrelation among sickness funds, care providers and

patients. Among the issues addressed were the delegability of doctors’ services, documentation requirements in therapy, the targeted attempts of sickness funds to persuade patients to switch to less expensive care providers, issues of competition law as well as the legal relationship between other service providers and pharmacies.

Sectoral Interest Group “Medical Technology Implants” (FBMTI)

The overall focus of this sectoral interest group is on the field of endoprosthetics. FBMTI’s activities addressed the impact of DRGs on the endoprosthetics industry and also their further development, the analysis of health political developments in the implants sector, and congress management as well as public relations and educational work. The group was also engaged in an intensive exchange of ideas with the medical expert societies.

Sectoral Interest Group “Modern Wound Care Products” (FBMW)

FBMW continued its educational efforts on the prescribability, reimbursability and economic efficiency of modern, or hydro-active, wound care products (e.g. gels). Thus, the group updated the dressing material section of the so-called “Yellow List”. FBMW also annually organizes informative events on “Hydro-active Wound Care” for decision makers in Statutory Health Insurance. As a supplementary measure, a study on the situation of “wound care in Germany” was carried out on behalf of BVMed.

Sectoral Interest Group “Renal Replacement Therapy” (FBNE)

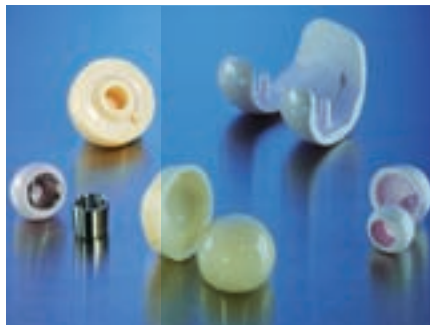
FBNE was established in May 2006 to represent the interests of suppliers of life-support technologies for renal replacement therapy. Next to renal transplantation, dialysis procedures provide the only means of keeping patients suffering from chronic renal disease alive. The group’s main concern is to inform and educate the public on the value of these life-supporting medical technologies and on the basic conditions these services are subject to.

...

- Medical Technology Implants (FBMTI)
- Minimally Invasive Procedures (FBMIN)
- Modern Wound Care Products (FBMW)
- Renal Replacement Therapy (FBNE)
- Peripheral Vascular Medicine (FBPG)
- Absorbing Incontinence Care (Manufacturers) (FBI)
- Practice Supplies, Prescribable Supplies, Medical Dressings (FBSRV)
- Supply of Sterile Goods (FBSV)
- Radiation Sterilization (FBS)
- Ostomy/Incontinence Care (FBSI)
- Therapeutic Apheresis (FBTA)
- Tracheostomy/Laryngectomy (FBTL)
- Spine Surgery (FBSC)



Help for the Musculoskeletal System:
Short Stem Prosthesis for the Hip, Artificial Hip Joint



Ceramic Implants



Ankle Joint Prosthesis

Working Groups

Electronic Health Card (PG eGeK)

Electrostimulators (PG ESG)

Interstitial Brachytherapy (PGIBT)

Intermittent Catheterization (PG ISK)

Guideline Innovative Medical Devices (PG LIMP)

Medical Care and Remuneration (PG MVV)

PVC (PG PVC)

Reuse (PG Reuse)

Material Costs and Outpatient Surgery (PG SAO)

Sets (PG Sets)

Tissues (PGT)

VAD/Artificial Heart (PG VAD)

Sectoral Interest Group “Peripheral Vascular Medicine” (FBPG)

FBPG supports the promotion of medical technologies in the peripheral vascular system, such as PTA technologies or occlusion systems. The group also participates in the maintenance of the scientific register “PTAREG”, which records the treatment of patients suffering from peripheral occlusive arterial disease before or after undergoing PTA.

Sectoral Interest Group “Absorbing Incontinence Care (Manufacturers)” (FBI)

This group’s efforts were mainly focused on achieving the consideration of the recent increase in value added tax in the stipulation of federal reference prices and on the maintenance of the quality of care at cost-covering reimbursement rates. The group was also concerned with analyzing the effects of the current healthcare reform and the development of nationally uniform quality standards for the long-term protection of the quality of care in absorbing incontinence care.

Sectoral Interest Group “Practice Supplies, Prescribable Supplies, Medical Dressings” (FBSRV)

This sectoral interest group continued its regular talks with sickness funds and SHI doctors’ associations on the subject of “reimbursement of medical material costs for office-based SHI physicians”. The impact of the so-called “Economic Optimization of Pharmaceutical Care Act” (AVWG) on the prescription behavior of physicians was in the center of the group’s work.

Sectoral Interest Group “Supply of Sterile Goods” (FBSV)

FBSV constitutes the superordinate group for all questions pertaining to the requirements on sterile goods and their application. If required, specific issues are followed up in FBSV’s sub-groups or in the sectoral interest groups “Ethylene Oxide Sterilization” (FBEO) and “Radiation Sterilization” (FBS). Since the major part of the international standards for sterilization procedures and sterile product packaging have been reviewed, a seminar in March 2007 will inform on the new requirements applying to “sterile medical devices”.

Sectoral Interest Group “Ostomy/Incontinence Care” (FBSI)

This group’s efforts in 2006 were centered on the introduction and review of federal reference prices for draining incontinence products. Thus, a significant improvement of the proposed reference prices could be achieved by means of FBSI’s expert statements. Current issues addressed are the impact and implementation of the health-care reform as well as the development of nationally uniform quality standards for the long-term protection of the present quality of care.

Sectoral Interest Group “Therapeutic Apheresis” (FBTA)

The members of this group are providers of technologies for extracorporeal blood purification. Approval of apheresis therapies is greatly impeded by the fact that these technologies are often successfully used in the treatment of rare diseases, so-called “orphan diseases”, thus rendering a customary statistical assessment inapplicable. The group is committed to improving the available data in this area.

Sectoral Interest Group “Tracheostomy/Laryngectomy” (FBTL)

The group is committed to maintaining and protecting the individual care of tracheotomized and laryngectomized patients, particularly in outpatient care. In order to be able to ensure this quality of care also in the medium and long term, the group is currently developing nationally uniform quality standards. Further issues are billing and co-payment problems, the reuse of suction devices as well as the current healthcare reform and its possible impact on the care of tracheotomized and laryngectomized patients.

Sectoral Interest Group “Spine Surgery” (FBSC)

FBSC, which is mainly concerned with medical technology procedures on the spine, compiled and published a coding guideline for the DRG system in cooperation with the relevant medical expert societies. The further education and training of the next generation of doctors is to be advanced with these technologies in the future.



Artificial Knee Joint



Artificial Shoulder Joint



Intervertebral Disk Implants



Working Groups and Sub-Groups

Working Group “Decubitus Forum” (DF)

The Decubitus Forum advocates a fair implementation solution for the introduction of the new product group 11 “anti-decubitus aids” and the associated cancellation of the former product group 11. Moreover, the forum organizes seminars for affected care providers. In addition, the forum compiled a guideline on the “Selection of the right anti-decubitus aid” and an information card on the prescribability and reimbursability of these products.

Working Group “Electronic Health Card” (PG eGeK)

The working group “Electronic Health Card” of BVMed’s sectoral interest group “Health Insurance Law for Care Providers” (FBLL) is concerned with all matters pertaining to the electronic health card and the so-called e-prescription. The group prepared a proposal for the assignment of health professional cards to other types of care providers and the providers of medical supplies.

Working Group “Reuse” (PG Reuse)

The efforts of this working group concentrate on the practice of reprocessing and reusing single-use medical devices contradictory to the manufacturer’s instructions. In the reporting period, the members of PG Reuse mainly addressed the question how the reprocessing of single-use devices, which is carried out without knowledge of the manufacturer’s specifications for the device, can be certified as a validated procedure. The members also commented on the recommendation of the Robert Koch Institute for “Infection Prevention in Dentistry” and took up the discussion at the conference on the “Reuse of Medical Devices” in October 2006.

Working Group “Material Costs and Outpatient Surgery” (PG SAO)

PG SAO coordinates proposals for the inclusion of medical technologies in the service catalog for outpatient surgery and the reimbursement catalog for office-based outpatient care (Einheitlicher Bewertungsmaßstab – EBM).

Working Group “Tissues” (PGT)

PGT devoted particular attention to the question as to what the future regulatory framework for companies intending to place products containing cells or tissues of human origin on the market will look like. Across Europe, the situation is marked by highly heterogeneous requirements, the uncertainty of whether these innovative products and procedures will be reimbursed by the health insurance funds in the first place, as well as a wide range of new legislative projects.

Working Group “VAD/Artificial Heart” (PG VAD)

This working group is dedicated to ensuring an appropriate implementation of innovative cardiac support systems and cardiac replacement technologies (artificial hearts). PG VAD adjusted its previously developed coding tool for the assignment of technologies to DRGs for 2006. The group is currently monitoring the preparation of an HTA report of the German Institute of Medical Documentation and Information (DIMDI).

Working Group “Sharps Injuries” (AG NSV)

The members of AG NSV provided briefings on the new version of the “Technical Guideline for Biological Working Materials” (TRBA 250) and commented on the flaws of the regulation. The group also addressed the question as to how the knowledge of the risk of sharps injuries and of ways of protecting oneself from that risk can be incorporated in the vocational training of future nursing staff from the very start. In order to improve the inadequate data available, study projects were supported and existing data on the application of instruments was made available.

Working Group “Legal Issues” (AG Legal Issues)

As a sub-group of BVMed’s sectoral interest group “Health Insurance Law for Care Providers” (FBLL), this group addresses complex legal issues with a particular focus on health insurance law. At the top of the group’s agenda was the development of alternative proposals for articles 33, 126 and 127 of Book Five of the German Social Code from the perspective of BVMed’s member companies as well as the “waiving of statutory co-payments” by the care providers.

Sub-Groups

- Billing of FBLL
- Suction Devices
- Active Implants (AG AI)
- Barcodes (AG Barcodes)
- DRG (AG DRG)
- Electric and Electronic Devices Act (AGEG)
- Communication (AGK)
- Guidelines (AGL)
- Lp(a)-Apheresis (AGLp(a))
- Sharps Injuries (AG NSV)
- REACH (AG REACH)
- Legal Issues (AG Legal Issues) of FBLL
- Ostomy/Incontinence Care (AGSIV)



BVMed's Head Office in Berlin



BVMed Chairman of the Board Anton J. Schmidt and BVMed Board Member Dr. Meinrad Lugan in Dialog with Federal Health Minister Ulla Schmidt



BVMed – At your Service!

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Director of the Medical Division of Paul Hartmann AG

Carsten Clausen

Member of the Management Fresenius Kabi Deutschland GmbH

Dr. Manfred W. Elff

Vice President Central Europe and Managing Director SORIN GROUP Deutschland GmbH

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BVMed's Board of Directors at the Annual General Meeting in 2006



BVMed Summer Reception in the Courtyard of the Association's Head Office



State Secretary Dr. Klaus Theo Schröder at BVMed's Autumn Meeting in 2006

BVMed – Our Services for You

BVMed represents more than 200 industry and trade companies. 20 of the largest medical device manufacturers worldwide in the consumer goods sector are, among others, organized in the association. Its scope comprises the entire sector of medical dressings, technical aids such as ostomy and incontinence products or bandages, plastic disposable items such as syringes, catheters and cannulae as well as the implants sector of intraocular lenses, hip, knee, shoulder and spinal implants, heart valves and defibrillators and even artificial hearts. Homecare services and biotechnology procedures, such as tissue engineering, are further fields of activity.

As a trade association, BVMed promotes and represents the combined interests of the medical technology industry and trade companies. In various sectoral interest groups, focus groups, and working groups, the association offers its members a platform for a constructive dialog and exchange of views. BVMed represents the concerns of its member companies to policy makers and the public in general. This is achieved not only by information and public relations work, but also by participation in the development of laws, guidelines and standards. BVMed's services can be subdivided into four sectors:

1. Organization

BVMed carries out the joint formation of opinion in more than 50 committees covering specific subjects. You will find more information on the committees in this brochure starting at page 15 et seq. An up-to-date overview of BVMed's expert committees is available on the internet at www.bvmed.de (About BVMed).

2. Consultancy

BVMed's experts are ready to offer accurate advice to members on such diverse topics as the Medical Devices Act, social legislation, the DRG law, the Act on Advertising in the Healthcare System, standardization projects, or ordinances.

3. Information

BVMed's multi-faceted information service is evident in both its internal and external communications. Examples of BVMed's communication efforts include:

Internal communication

- :: General circular letters to all members
- :: special circular letters for the individual committees
- :: weekly newsletter
- :: weekly chart pool
- :: monthly report
- :: extranet for member companies

External communication

- :: Website www.bvmed.de
- :: brochures, information cards
- :: special BVMed conferences
- :: MedInform conferences
- :: training seminars (Medical device consultants, seminars on Statutory Health Insurance)
- :: press releases and conferences
- :: press seminars
- :: TV Service Medical Technology

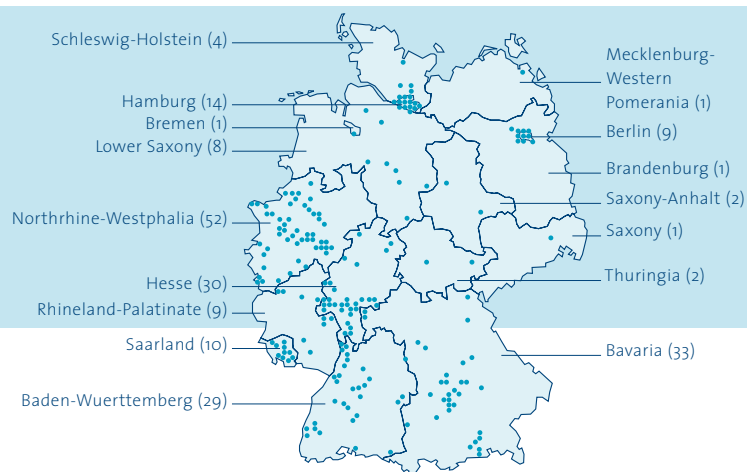
4. Representation

BVMed represents the interests of the medical technology sector. Important aspects are, among others: Political marketing and individual policy talks, maintenance and support of networks, parliamentary evenings, background talks, participation in parliamentary hearings, representation in committees, boards of trustees, commissions, etc.

How can your company become a member of BVMed?

The terms and conditions for membership of BVMed are stated in § 3 of the BVMed statutes, which you will find on the internet at www.bvmed.de (About BVMed) or receive from BVMed on request. Applications for membership must be submitted in a letter to the Director General of BVMed. Please contact us. We look forward to helping you!

Regional Distribution of BVMed's Member Companies



As in March 2007: 206 members – current list available at www.bvmed.de

BVMed Membership List

*3M Medica Zweigniederlassung der
3M Deutschland GmbH

A

*aap Implantate AG
Abbott GmbH & Co. KG
Abbott Vasculare Devices
Abena Hygiene GmbH
Abiomed Europe GmbH
ACRITEC Gesellschaft für ophthalmologische
Produkte mbH
ADL Anti Dekubitus Lagerungssysteme
GmbH
*AESCLAP AG & CO. KG
AirSystems Medizinische Produkte GmbH
ALCON PHARMA GmbH
American Medical Systems
Deutschland GmbH
amg Vascular Products GmbH
*AMO (Advanced Medical Optics)
Germany GmbH
AMOENA GmbH & Co. KG
Medizin-Orthopädie-Technik
Andreas Fahl Medizintechnik-Vertrieb GmbH
Ansell GmbH
ARROW Deutschland GmbH
ASSAmed GmbH
Assist Heimpflege-Bedarf GmbH
Astra Tech GmbH
ATMOS MedizinTechnik GmbH & Co. KG
Atos Medical GmbH
AURELIA Medical Handel GmbH

B

B + P Beatmungs-Produkte GmbH
*B. BRAUN MELSUNGEN AG
*Bausch & Lomb Surgical GmbH
Baxter Deutschland GmbH
Becton Dickinson GmbH
Beiersdorf AG
Berlin Heart AG
BGS Beta-Gamma-Service GmbH & Co. KG
Biomet Deutschland GmbH
*BIOTRONIK GmbH & Co.
*Boston Scientific GmbH
*Bristol-Myers Squibb GmbH & Co. KGaA
ConvaTec Vertrieb GmbH
*BSN medical GmbH

C

*C. R. Bard GmbH
Cardinal Health Germany 206 GmbH
(formerly: Allegiance Healthcare
Deutschland GmbH)
*CeramTec AG
Geschäftsbereich Medizintechnik
Chemische Fabrik Kreussler + Co. GmbH
Clinical House GmbH
*Coloplast GmbH
Coltène / Whaledent GmbH + Co. KG
(formerly: ROEKO GmbH + Co. KG)
Cook Deutschland GmbH
*CORDIS Medizinische Apparate GmbH
*Corin Germany GmbH
CORNEAL GmbH
curasan AG
Cyberonics – Devices for Epilepsy

D

Dansac GmbH
*DePuy Orthopädie GmbH
DEWE + CO Verbandstoff-Fabrik
Dr. Wüsthoff GmbH & Co. KG
DIAMED Medizintechnik GmbH
*Domilens GmbH
DOT GmbH
Dr. Ausbüttel & Co. GmbH

E

*Edwards Lifesciences Services GmbH
EMKA Verbandstoffe GmbH & Co. KG
*ETHICON GmbH Johnson & Johnson

F

FOR LIFE Produktions- und Vertriebsgesell-
schaft für Heil- und Hilfsmittel mbH
Franz Kalff GmbH
*FRESENIUS AG
Fritz Osk. Michallik GmbH & Co.
Fuhrmann Verbandstoffe GmbH

G

gambro dialysatoren GmbH & Co. KG
GANZONI GmbH
GARANTOL Products Detia Freyberg GmbH
*GE Healthcare Accessories & Supplies,
Medimex Medicalis
Genzyme GmbH

*GerroMed Pflege- und
Medizintechnik GmbH
Given Imaging GmbH
*GUIDANT GmbH

H

HAEMONETICS GmbH
Hakle-Kimberly Deutschland GmbH
HANS HEPP GmbH & Co. KG
HEIMOMED Heinze GmbH & Co. KG
Heraeus Medical GmbH
HMT Medizintechnik GmbH
*Hollister Incorporated
Niederlassung Deutschland
Holthaus Medical GmbH & Co. KG
HOMANN – MEDICAL GmbH u. Co. KG
HSC Home SUPPLY +
Care Beteiligungs GmbH
HTMA Home Therapie Management GmbH
*HumanOptics Deutschland GmbH & Co. KG

I

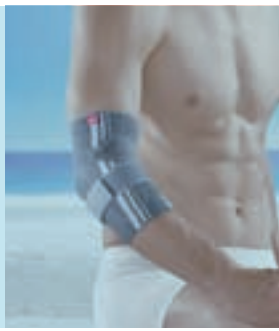
IIP-Technologies GmbH
Impulse Dynamics GmbH
INAMED Aesthetics GmbH
INVATECH Gesellschaft für fortschrittliche
Medizintechnik mbH & Co. KG
Isotron Deutschland GmbH

K

Kaneka Pharma Europe N. V. German Branch
Karl Beese (GmbH & Co.)
Karl Otto Braun KG
KCI Medizinprodukte GmbH
KEIMED GmbH (HSC)
Kettenbach GmbH & Co. KG
KLUGE medical Gesellschaft für
Hygiene- und Medicalprodukte mbH
*KRAUTH medical KG (GmbH & Co.)
KREWI Medical Produkte GmbH
Kyphon Deutschland GmbH

L

Leina-Werke GmbH Verbandstoffe Medical
*LMA Deutschland GmbH
*LogoMed GmbH
*Lohmann & Rauscher International GmbH &
Co. KG
Ludwig Bertram GmbH



Bandages support and help heal: e.g. Ankle Joint, Elbow or Back

M

- MacoPharma International GmbH
- MagForce Nanotechnologies AG
- Maimed Medical GmbH & Co. KG
- Maquet Cardiopulmonary AG
- Mathys Orthopädie GmbH
- medac GmbH – Gesellschaft für klinische Spezialpräparate
- *medi GmbH & Co. KG
- *Medi-Globe GmbH
- Medi1one Medical Großhandels GmbH
- Medical Service Vertriebs-GmbH
- Medilog Handelsgesellschaft mbH
- METHODIC Bernd A. Harren KG
- *Medtronic GmbH
- megro GmbH & Co. KG
- MENTOR DEUTSCHLAND GmbH
- mepro Medizinische Produktion GmbH
- Merete Medical GmbH
- Mundipharma GmbH
- *Mölnlycke Health Care GmbH

N

- Nestlé Clinical Nutrition GmbH
- neurotech Bio-Medical Research GmbH
- NOBA Verbandmittel Danz GmbH u. Co. KG
- noma med GbR
- Novartis Nutrition GmbH
- Novo Klinik-Service GmbH

O

- Oncura GmbH
- OptiMed Medizinische Instrumente GmbH
- ORIPLAST Gebr. Kraye GmbH
- ORMED GmbH
- OSSACUR AG
- Otsuka Pharma GmbH
- Otto Bock HealthCare GmbH, Betrieb Maintal

P

- P.J. Dahlhausen & Co. GmbH
- Pajunk Medical Produkte GmbH
- Pall GmbH Medical
- PAPER-PAK GERMANY GmbH
- PARAM Großhandelsgesellschaft mbH
- PAUL HARTMANN AG
- Peter Brehm GmbH Chirurgie-Mechanik

*pfm Produkte für die Medizin

- Aktiengesellschaft
- Pfrimmer Nutricia GmbH
- Phadimed GmbH & Co.KG
- PlasmaSelect AG
- *Plus Orthopedics AG
- PMT Präzision-Medizin-Technik GmbH
- POLYTECH Ophthalmologie GmbH
- *POLYTECH-SILIMED Europe GmbH
- PULSION Medical Systems AG

Q

- Q-MED GmbH

R

- Radi Medical Systems GmbH
- Raguse Gesellschaft für medizinische Produkte mbH
- *Raumedic AG
- rehaVital Gesundheitsservice GmbH
- Rentex Vertriebs GmbH & Co. KG
- Resorba Clinicare GmbH
- *Ruth Cegla GmbH & Co. KG

S

- SANDER Chemisch-Pharmazeutische Fabrik GmbH
- Sangro Medical Services GmbH
- *Sanicare GmbH
- Sanitätshaus Aktuell GmbH
- SCA Hygiene Products GmbH
- SENGEWALD Klinikprodukte GmbH
- *servoprax GmbH
- Servox AG
- SFM Süddeutsche Feinmechanik GmbH
- Signus Medizintechnik GmbH
- *Smith & Nephew GmbH
- *Smiths Medical Deutschland GmbH
- *SÖHNGEN – W. Söhngen GmbH
- Sorin Group Deutschland GmbH
- Spring Medical Wilhelm Spring GmbH & Co.
- St. Jude Medical GmbH
- Sterigenics Germany GmbH
- Stryker Howmedica GmbH
- SYNTHESE GmbH
- System France

T

- *TECHNOMED Gesellschaft für med. und med.-techn. Systeme mbH
- Teleflex Medical GmbH (Willy RÜSCH GmbH)
- *TERUMO (DEUTSCHLAND) GmbH
- The ROHO Group – ROHO International, Inc.
- *Thomas Hilfen für Behinderte GmbH & Co. Medico KG
- Thoratec Europe Ltd.
- *THUASNE DEUTSCHLAND GmbH & Co. KG
- Tornier GmbH
- *TRACOE medical GmbH
- Tutogen Medical GmbH
- *Tyco Healthcare Deutschland GmbH
- Tytex GmbH

U

- UDO HEISIG GmbH
- *URGO GmbH
- URSAPHARM Arzneimittel GmbH & Co. KG

V

- Vereinigte Papierwarenfabriken GmbH
- Veritas Medizintechnik GmbH
- Vitatron GmbH
- VYGON GmbH & Co. KG

W

- W.L. Gore & Associates GmbH
- Waldemar Link GmbH & Co. KG
- WaveLight AG
- WERO-medical Werner Michallik GmbH & Co. KG
- Wilhelm Julius Teufel GmbH

Z

- *Zimmer Germany GmbH

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 Further Pictures: We would like to thank the companies marked with an asterisk* for the pictures they provided. More pictures of products and applications are located on the internet at www.bvmed.de (Pictures).

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