

The Medical Technology Companies

∴ ∴ ∴ ∴ **BVMed**
Enhancing Health.

Annual Report 2005/06





Medical Technologies improve People's Quality of Life and save Lives in Emergencies

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Anton J. Schmidt
Chairman of the Board of BVMed

Introduction

Medical Technologies as Part of the “Competence Center for Health”

The health economy is at the very top of the political agenda. It is increasingly appreciated as the growth market and significant employment factor it is. The coalition agreement of the new government states: “Healthcare is a dynamic economic sector with a high degree of innovation capability and considerable economic significance for Germany as an investment and industrial location.”

The health economy is becoming increasingly aware of medical technologies – a fact which can be, for instance, attributed to various studies undertaken by the Federal Ministries of Economics and Research as well as by the European Commission.

For us, the medical technology companies represented by BVMed, this is an encouraging development as it will lead to a stronger appreciation of the significance of medical technologies for high-quality patient care and an efficient and future-proof healthcare system. Most of the German parties also underscored the economic impact of this sector by explicitly mentioning medical technology in their election programs.

The conditions are favorable: 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 prerequisites for steering new products and procedures toward marketability.

However, there are considerable deficits in Germany when it comes to the introduction of innovations into the reimbursement systems, so that they may then

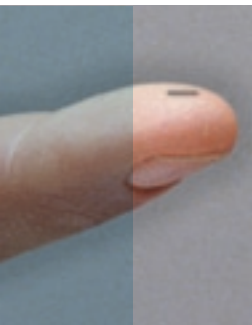
reach the patients in a timely manner. We mean to rise to this challenge in a joint effort with politicians, sickness funds, hospitals and all healthcare professionals. Now, the political framework must be created so that medical technology in Germany can maintain its leading position.

From our perspective, a long-term reorientation of health policy is called for, including increased competition, more freedom of choice for the medically-insured, and less regulation for the companies, doctors and hospitals. We must bridge the gap between competition on the one side and solidarity on the other. We must improve the general conditions for research and development. Above all, we need more outcome research. We need an altogether more innovation-oriented climate, so that innovative medical technology treatment methods and procedures get to the patients in good time.

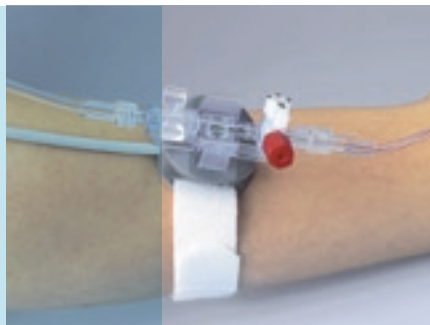
The medical technology companies can then further improve the healthcare situation of the patients with their products and procedures, be an important driving force for the health economy and contribute to establishing Germany as a “competence center for health”.

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 2006), some 210 industry and trade companies are represented by BVMed. Please find a complete list of BVMed's members on pages 22/23. In 2005, 17 companies joined BVMed. At the beginning of 2006, one further company became a member of the association. This is up against 10 withdrawals in 2005.

Market Development

In 2005, BVMed's member companies reported an increase in turnover of 2 per cent. In 2004, turnover had increased by 1.5 per cent. In the preceding years, turnover growth had been significantly stronger at 3.9 per cent in 2003 and 6.5 per cent in 2002. Germany is thus lagging far behind the world market development, which is at about 7 per cent.

Development in Subsectors

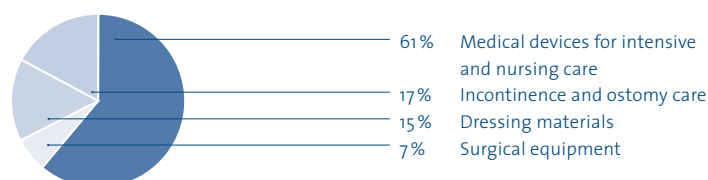
Especially the medical technical aids sector has been quite restrained. Ostomy and incontinence aids stagnated with a slight turnover growth of only 0.2 per cent compared to 2004, which had been a particularly bad year for the medtech aids sector. Dressing materials even reported a decrease of 0.1 per cent over the previous year, whereas the development in other subsectors was slightly positive: The category "single-use surgical equipment" increased by 2.8 per cent. Turnover growth in the areas "single-use devices, intensive care medicine, nursing items" was at 4 per cent. This rise in turnover, however, is mainly based on volume growth.

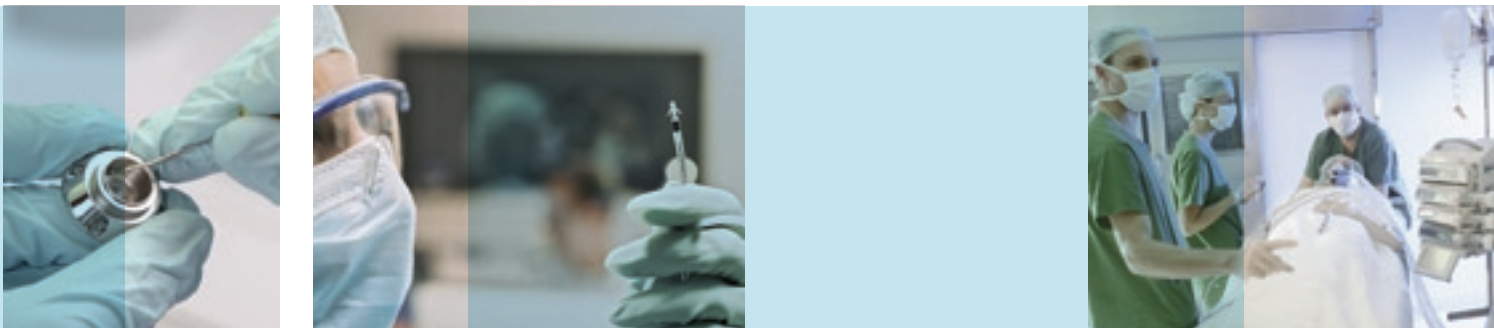
Results of a Membership Survey

In November 2005, BVMed conducted a comprehensive industry survey, in which 111 member companies (54 per cent) participated.

- :: The outlook on the year 2006 is somewhat optimistic. Some 43 per cent of the companies expect an improved economic development, while about 35 per cent estimate that it will remain unchanged. 22 per cent, however, fear a change for the worse.
- :: Participants name the following as the most severe restraints on the industry's development: the mounting pressure on prices due to purchasing cooperatives (73 per cent) as well as the continuing imposition of budgets (72 per cent) and the financial deficit of the health insurance funds (57 per cent). Almost half the member companies lament an altogether anti-innovation climate in Germany as well as escalating bureaucracy. A quarter is affected by the new federal reference prices for med-tech aids and the rising energy and raw material prices.
- :: 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 (65 per cent) and engineers (56 per cent), the high level of patient care (65 per cent) as well as the high standard in clinical research (56 per cent). The speedier market approval as compared to the United States is named as an advantage by 37 per cent. The low level of reimbursement in Germany as compared to other European countries is the main source of criticism.
- :: The medical technology companies represented by BVMed invest an average 7 per cent of their turnover in research and development. Almost 20 per cent invest even more than 10 per cent!
- :: Some 47 per cent of the companies state that they have created more jobs than in the previous year, with 11 per cent claiming a significant increase. On the other hand, 27 per cent had to cut jobs. Compared to the previous year, this represents a mild improvement of the job situation in Germany.
- :: From the new government, BVMed's member companies expect above all increased freedom of choice (57 per cent) and more individual responsibility of the medically-insured (50 per cent) as well as a deregulation campaign (51 per cent). 45 per cent advocate an outcome-oriented remuneration of healthcare services.

BVMed Sales Structure





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

Industry Report Medtech 2005/06

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. Some 240 billion Euros in total are spent on health. This represents a share of more than 11 per cent of the gross domestic product, thus making healthcare an even more significant sector than, for instance, the automotive industry (9.7 per cent 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 2003. This was reported by the German Federal Statistical Office in its health expenditure statistics. Of this amount, some 13 billion Euros account for the outpatient sector, including, for instance, medical technical aids, and 7 billion Euros for the inpatient sector. This amount does not include dental products and major medical equipment (capital goods). Further key figures of the sector: The production of medical technology in Germany comprised 14 billion Euros in 2003 (source: medical technology study of the Federal Ministry for Education and Research). In export, Germany, with a world trade share of 14.6 per cent, ranked second worldwide behind the USA (30.9 per cent) but distinctly ahead of Japan (5.5 per cent).

Employment Figures

The medical devices sector employs more than 108,000 people in some 1,100 companies (with more than 20 employees). This represents 2 per cent of all employees in the manufacturing industry. According to a new European study this figure is even higher, indicating 145,000 jobs. 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.

Growth Market Medical Technologies

The medical technology sector is a global growth market. Progress in the field of medical technology, demographic changes with an increasing number of older people and the evolved concept of health will keep it that way. The demand for health services will continue to rise steadily. Patients are increasingly prepared to invest in their health. A study of investment banker Goldman Sachs expects an average profit growth of 13 per cent for the entire medtech sector over a term of five years (Financial Times Germany of 15 March 2005, page 32). According to the newspaper, the sector was presently effecting 60 per cent of the pharmaceutical companies' total revenues already. "For the long run, a change in the lead is already becoming apparent", writes the Financial Times.

World Market for Medical Devices

The world market for medical devices amounted to 184 billion Euros in 2003. 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 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 per cent 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 per cent, that of the manufacturing industry to a total of 3.8 per cent (Frankfurter Allgemeine Zeitung of 26 April 2005, page 13).



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

Market Conditions for Medtech: Strengths and Weaknesses

Market Conditions – The Pros

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.

Market Conditions – The Cons

There are, however, considerable 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. One example for this is the drug-eluting stent, which keeps narrow or blocked vessels permanently open. This innovation is not only established as a standard treatment in the United States, but also in most European countries, with a penetration rate of currently 75 per cent in the US, 60 per cent in the United Kingdom and even 76 per cent in Switzerland. Germany, with a rate of only about 20 per cent, is lagging far behind the rest of the western industrial nations.

Utilizing the Potential of Medical Technologies as a Driving Force for Growth

In BVMed's estimation, the dynamic change of the medical possibilities 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. We must improve the general conditions for research and development. Above all, we need more outcome research. We need an altogether more innovation-friendly climate, so that innovative medical technology treatment methods and procedures get to the patients without delay.

Thus, BVMed calls for the removal of the presently existing innovation restraints, such as the lacking transparency in the decision-making processes of the Joint Federal Committee, the imposition of sectoral budgets or the current lack of quality standards for medical treatments. We require the clear will to introduce innovations into the German healthcare system and to establish processes for their timely adoption. This can only happen if the policy-makers act accordingly – by freeing the healthcare system from excessive bureaucracy and allowing it to benefit from deregulated and liberalized healthcare markets. Medical technology innovations can then be an important driving force of the health economy and contribute to establishing Germany as a “competence center for health”.

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 the 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 length of hospital stays and a reduced number of sick days.



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

Health Policy

Healthcare Reform

The year 2005 was dedicated to the Bundestag elections, which took place in early autumn. One major issue of the election campaign was the future financing of the German healthcare system. Two concepts were in the center of controversy: the "citizens insurance" (Social Democrats) and the "health premium" (Christian Union). The new government of Christian Union and Social Democrats must now find a joint approach for securing a sustained funding of the healthcare system.

Development of SHI Finance

The financial situation of Statutory Health Insurance (SHI) developed positively in 2005. A surplus of some 1.78 billion Euros could be "effected". This, however, can be mainly attributed to a tax-based government subsidy. According to the new government's plans, this subsidy is to be discontinued by 2008. The surplus is mostly spent on the reduction of the SHI's accumulated financial deficits and will not be used to the benefit of medical care. In terms of expenditures, drugs incurred a high amount of additional costs while expenditures on medical technical aids have stagnated. Expenditures in the clinical area are growing moderately, which is due to the conversion to the new hospital reimbursement system. Its crumbling means of income, even further aggravated by the conversion to the new regulations for unemployment benefits commonly referred to as "Hartz IV", will remain the main challenge of Statutory Health Insurance.

Impact of the Healthcare Reform

The new co-payment regulations, which also affect the dressing materials and medtech aids sectors, as well as the practice fee have produced visible results. The decrease in the total number of visits to doctors' offices has affected the prescription and referral behavior of the physicians.

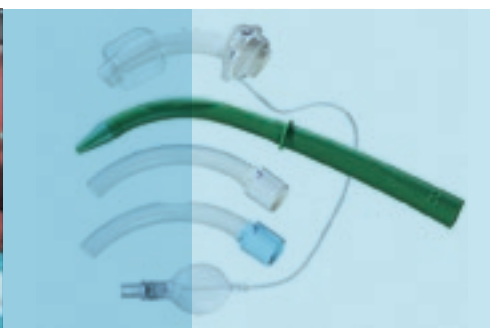
Evaluation of Services by the Joint Federal Committee (Gemeinsamer Bundesausschuss – G-BA)

The code of procedure originally issued by the G-BA posed a major threat to the approval regulation for innovations in hospitals. This code of procedure sought

to replace the principle "permission with the reservation of prohibition", which had until then applied to the inpatient sector, in a way that would have prevented the introduction of new examination and treatment methods for the time being. A new method could only have been introduced into the hospital sector if exclusively applied within the scope of studies. Moreover, these studies were to establish qualified proof of a method's benefit on the basis of the highest evidence level. This would have set up insurmountable obstacles for technical advancement in Germany, and innovation would have been virtually excluded from patient care in the hospital sector. After a fair amount of outside intervention – among others by BVMed – the members of the G-BA agreed on keeping the principle of permission with the reservation of prohibition in effect, if with additional requirements.

BVMed's Activities in Health Policy

In the run-up to the elections in September 2005, BVMed presented an "Agenda for Innovation in Medical Technology" to the political parties in order to promote innovation and to maintain the currently high level of healthcare in Germany. In this agenda, BVMed expressed concrete recommendations for action that were to be considered in the drafting of the parties' election programmes. BVMed is pressing for more outcome research in order to comprehensively portray the total costs of a therapy as well as its benefits to the patients and the economy. Other suggestions are aimed at the new hospital reimbursement system, which must be open to new methods of treatment, as well as at the Joint Federal Committee's procedures for technology assessment, which must be clear and transparent, concluded in a more timely fashion and harmonized across Europe. All in all, the value of innovative medical technologies must be more strongly appreciated. A first achievement of BVMed's efforts in this area is that the significance of medical technologies for an efficient and future-proof healthcare system has been increasingly acknowledged in the past months. Most parties explicitly and quite favorably mentioned the field "medical technology" in their election programs. You will find the agenda's core statements on nine subject areas on the next page.



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

Agenda for Innovation in Medical Technology

Impact of Medical Technologies

The value of innovative medical technologies must be more strongly appreciated in German healthcare. Medical technologies can contribute to an altogether more effective healthcare system. They lead to shorter recovery times and enable patients to return to work more quickly, thus creating an economic gain that must no longer be neglected. Therefore, medical technologies should not be devalued as a pure cost factor.

Health Policy

Health policy must provide incentives for innovation. One essential goal of the health insurance reform must be to provide all patients with access to the medical advancement and medical technological innovations they require without delay. It is recommended that the reimbursement catalogs covering medical technology services and products as well as their reimbursement prices be updated at an accelerated pace to encourage a more efficient application of medical technology.

Focus on the Patients

Efforts to streamline the German healthcare system must not lead to rationing measures that deprive patients of lifesaving therapies. The focus must be on the patient, also and especially in view of the expenditure situation and a possible income reform of Statutory Health Insurance in Germany. This would, above all, presuppose that doctors are able to make therapeutic decisions solely on the basis of their medical education.

DRG System

The new hospital reimbursement system must be open to new treatment methods. Flexible and non-bureaucratic solutions between contracting partners at a local level are called for. Only if the imposition of fixed budgets is discontinued can this system lead to more transparency and performance-oriented payment and only then can the healthcare system focus on people's medical needs. This would, for instance, also include that innovative therapies are only applied in those hospitals that are sufficiently equipped to perform leading-edge medical care in the first place. This specialization is cost-efficient and health politically intended.

Health Technology Assessment

The Joint Federal Committee's procedures of Health Technology Assessment (HTA) must be clear and transparent and also concluded in a more timely fashion. Industry must be more actively involved in the process. In order to achieve this, industry should, for instance, be able to file applications, have a say in HTA procedures (case-related nomination of experts) and raise objections to challenge negative decisions. Decisions on the Statutory Health Insurance coverage of medical technologies must be made in a timely and transparent manner according to clearly defined criteria.

Outpatient Remuneration System

We need a reform of the remuneration system in outpatient care which will allow for a fair and appropriate reimbursement by Statutory Health Insurance and reflect the true material costs incurred in a treatment. Patients must be allowed a range of options to take on more financial responsibility when it comes to innovative procedures.

Outcome Research

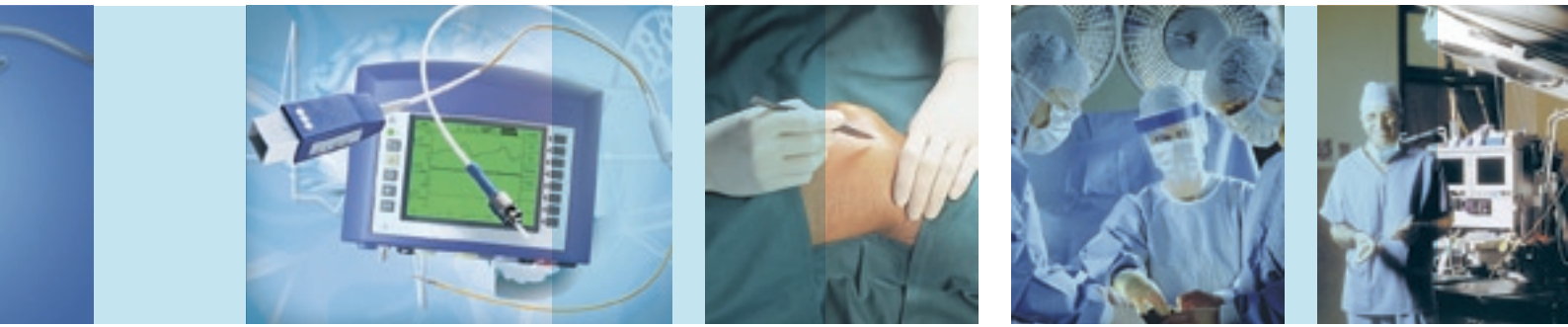
We need more outcome research in order to be able to comprehensively portray the overall costs of a therapy as well as its benefits for the patients and economy.

Medical Technical Aids

Care involving medical technical aids must remain unrestricted in the future, and a so-called "positive list" cannot be consented to. Bureaucracy must be removed from application procedures and processing must be accelerated. The expert knowledge of the trade and industry companies must be applied in the development of guidelines.

Homecare

Homecare serves the health political aim of "outpatient before inpatient". Therefore, adequate conditions must be created for this growing healthcare sector.



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

2005: The First Year in the Convergence Phase

Even in the transitional period from budget system to fully effective diagnosis related group (DRG) pricing system, an increasingly competition and performance-oriented mindset can be observed in the hospitals.

1,740 acute care hospitals, representing 95 per cent of those hospitals obliged to adopt the new system, were reimbursed on the basis of DRGs in 2005.

Germany has meanwhile evolved into one of the world leaders in the field of DRG reimbursement next to the United States, even although the new prospective payment system was only introduced as recently as three years ago. Effects are: a reduced length of hospital stays, more efficient process flows in patient care, consolidation processes. The resulting trend of specializing hospitals, mergers and privatizations has already reached the university hospitals.

G-DRG System 2006 and Regulatory Framework

The performance homogeneity of the DRGs has been further increased with the publication of the DRG catalog for 2006. The number of DRGs increased to 954, that of supplemental payments to 82, of which numerous include medical technologies. The basis for calculation was extended from 133 participating hospitals in the previous year to 214. This will make it easier to calculate the actual share of material (e.g. medical device) costs incurred by the patient.

New Procedures in the DRG System

The payment regulation for new methods of examination and treatment (Neue Untersuchungs- und Behandlungsmethoden – NUB) applies for the first time. The self-governing bodies charged the Institute for the Reimbursement System in Hospitals – in short DRG Institute (InEK) – with processing NUB applications filed by hospitals. By 31 October 2005, more than 4,000 individual applications had been duly submitted by the hospitals. Of these, 900 applications were classified as negotiable.

Only 26 therapy procedures met the NUB criteria. The remaining procedures could not be processed in time by InEK and can thus be negotiated locally. BVMed appeals to the self-governing partners to provide greater

transparency for the implementation of the new innovation clause. This is a touchstone for the acceptance of the new system, which must secure the timely adoption of innovative medical technologies in inpatient care.

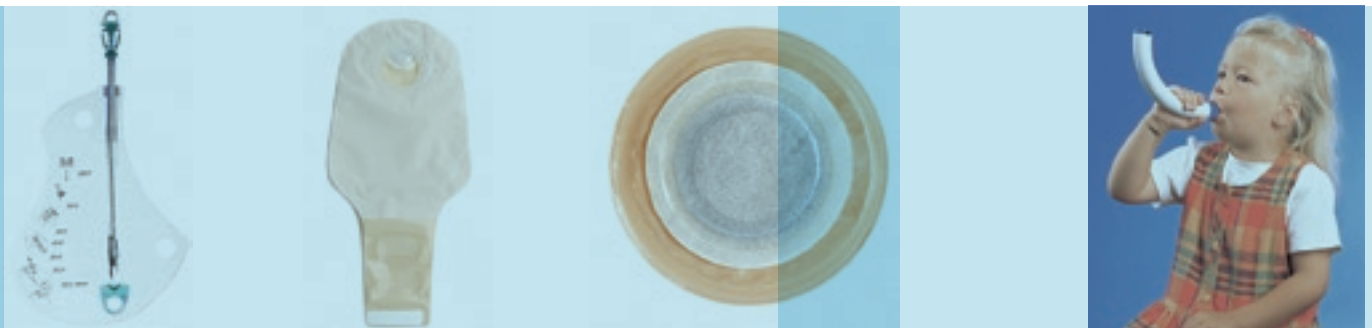
The DRG System after 2009

The convergence phase provides for a gradual change-over of the hospital-individual budget to a national pricing system. Excess DRG performance cases (above the case volume budgeted at the beginning of the year) will not receive payment for the full DRG until 2009. Until then, additional performance case remuneration will be gradually increased. From 2009, DRGs will be paid in full. The debate on the further DRG scope following the end of the convergence phase will begin in 2007 at the latest. BVMed will consequently demand an appropriate incorporation of medical technologies and continue its dialog with all stakeholders concerned in a constructive manner.

Hospital Purchasing Cooperatives

The economic challenges of the new reimbursement system also take their toll on the procurement processes in hospitals. For this reason, BVMed commissioned a study on the future relevance and consequences of hospital purchasing cooperatives for medical technology suppliers in Germany from the marketing consultancy firm Simon, Kucher & Partner. The study identifies medium-term development trends in German hospital purchasing and offers strategic recommendations for action for suppliers to successfully face the changes in the future market place.

The study concludes that the influence of hospital purchasing cooperatives will continue to grow strongly. The share of the medical technology suppliers' hospital sales effected through transactions with purchasing cooperatives will rise from some 40 per cent today to 90 per cent in 2010. The pooling of negotiating power in hospital purchasing is resulting in an ever increasing pressure on prices, which in turn creates entirely new demands on the sales and marketing activities of the medical device companies. The authors advise that competition should concentrate on the product and service elements and not on prices. The study can be downloaded at www.bvmed.de (Publications).



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

Technical Aids

Impact of the Healthcare Reform on the Technical Aids Sector

Even two years after the SHI Modernization Act came into effect, its consequences are felt quite acutely in the medtech aids industry. The health insurance funds' cost-saving measures affected both the manufacturers and the providers of care involving technical aids. As a result, only about 3.3 billion Euros were spent on technical aids in the first three quarters of 2005, representing a share of 3.1 per cent in the total expenditure of Statutory Health Insurance. In the first nine months of the previous year, this share had still amounted to 3.2 per cent.

Federal Reference Prices

The effects of the first federal reference prices, which have been in force since January 2005, were not long in showing themselves either. In consequence, many care providers were only able to provide for adequate patient care by implementing comprehensive rationalization measures. However, even operational or personnel restructuring measures are not always sufficient to maintain the present product and/or service quality in healthcare, unless the patient is prepared to accept the necessity of additional payments. In 2005, the national associations of SHI funds reviewed the federal reference prices already existing. BVMed actively supported the SHI funds in their reviewing efforts with up-to-date market analyses, with particular regard to ostomy care. The sickness funds arrived at the conclusion that there is merely a need for adjustment in reference prices for incontinence pads. The hearing for the assignment of reference price groups for draining incontinence products took place in 2005, followed by its publication in February 2006. Subsequently, the hearing proceedings for the stipulation of reference prices for draining incontinence products and pads were initiated. The new reference prices are scheduled to take effect on 1 July 2006.

Update of Product Group "Anti-Decubitus Aids"

At the beginning of 2006, the national associations of SHI funds updated various product groups (PGs) of the medical technical aids register, including PG 12 (Techni-

cal Aids for Tracheostomy), PG 15 (Draining Incontinence Aids), and PG 17 (Technical Aids for Compression Therapy). BVMed devoted particular attention to the update of PG 11 (Anti-Decubitus Aids).

For the first time, not only the structure but also the technical and medical requirements of this product group have been changed completely, so that PG 11 is to be closed down after a transitional period (31 July 2006). For 2006, updates of PG 09 (Electronic Stimulation Devices) and PG 03 (Application Aids) are planned, among others. All updates and amendments to the medical technical aids register can be viewed and/or downloaded at www.g-k-v.de, or www.internet.ikk.de/himi/.

Recent Case Law Involving the Medical Technical Aids Register

Due to recent case law developments (e.g. the judgment of the Federal Social Court on the C-Leg of 16 September 2004; the judgment of the European Court of Justice on the reimbursability of wheelchairs of 13 January 2005; or the judgment of the Higher Social Court of Northrhine Westphalia on ankle joint support systems of 20 September 2005) the following questions have returned to the center of discussion: What kind of evidence can be demanded by the national associations of SHI funds with regard to the adoption of products into the medical technical aids register? What is already covered by CE marking? The national associations of SHI funds filed an appeal against the ruling of the Higher Social Court of Northrhine Westphalia, so that the matter is now pending a decision by the Federal Social Court.

"Medtech Aids Communication Forum"

The representatives of medtech aids manufacturer and care provider associations as well as those of care provider communities regularly get together for a continuous exchange of ideas in the so-called "Medtech Aids Communication Forum", which was founded in mid-2005. The forum serves as a partner to policy makers, health insurance funds, prescribers and users in all questions of care involving medical technical aids. The forum's aim is to accelerate communication, optimize and safeguard the quality of care as well as to promote transparency and improve the flow of information.



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. However, the differentiation between the duties of health and long-term care insurance is not always clear and precise. Nevertheless, this must not lead to a relocation of services into long-term care insurance on account of the cost pressure in health insurance. As early as in the year 2000, this debate was spurred by the so-called “wheelchair ruling”. After the Federal Social Court had confirmed the sickness funds’ liability in several rulings, recent case law has been showing a trend towards transferring liability into long-term care insurance in the case of patients who were unable to lead a self-determined life. 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. Particular attention should be devoted to the growing significance of care models that require the qualified and professional provision of advice and support, such as pain or chemo therapy.

The Focus must be on Quality

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 fact that the focus in German healthcare is predominantly centered on cost-per-item considerations rather than on the overall cost of care per patient case is also evident in the revised pharmaceutical guideline on the reimbursability of oral supplement and tube feeding. The exclusion of disease-specific formulas, e.g. for patients suffering from diabetes, on account of the additional costs incurred by these special products failed to factor in the cost-saving benefits resulting from the prevention of secondary complications which are due to uncontrolled blood sugar levels.

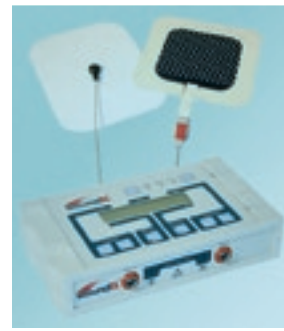
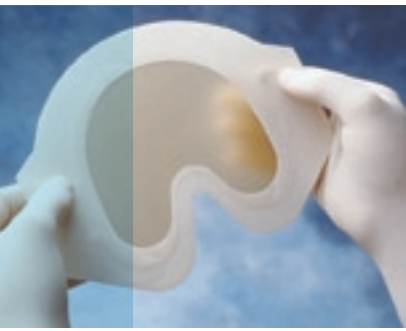
Electronic Health Card

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.

To date, 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

When the establishment of medical healthcare centers (Medizinische Versorgungszentren – MVZ) was legally anchored in Book Five of the German Social Code, there was a mood of euphoria among doctors. Ultimately, the development and advantage of MVZs is highly dependent on regional factors and thus, an area-wide implementation could not be achieved. At present, there are some 270 approved MVZs in Germany. The situation is quite different in integrated care contracts: Even although there is just 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. By the end of September 2005, the Federal Office for Quality Assurance had registered some 1,400 contracts accounting for a total of more than 370 million Euros in spending. The new government has already indicated its intention to extend the period of start-up funding for integrated care 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

The review of the European Union's "New Approach" directives is aimed at the legal alignment of 21 harmonization directives, which provide for the CE marking of industrial goods. This is supposed to strengthen the competitiveness of the European Single Market and improve pan-European market surveillance. However, this objective has proven to be hardly feasible, as the regulatory density in the sector of medical devices is incomparable to other sectors. Accordingly, compliance with a single European standard is sufficient for receiving CE mark approval for construction products. The significance of the CE mark thus varies considerably from directive to directive, which makes it much harder for EU citizens to appreciate the incomparably higher legal requirements on CE marking in the medical devices sector.

Amendment of European Directives

With considerable delay, the European Commission finally presented the stakeholders with a proposal on the amendment of directives 90/385/EEC (active implantable medical devices), 93/42/EEC (other medical devices) and 98/8/EC (biocides) at the end of December 2005. The most significant proposals for amendment pertain to conformity assessment, including technical documentation and the evaluation of the design of a product, a clearer specification of requirements on clinical evaluation, post-market surveillance, the compliance of custom-made devices with the requirements as well as the alignment of directive 90/385/EEC to directives 93/42/EEC and 98/79/EC (in-vitro diagnostic devices). From BVMed's perspective, the amendment directive will – contrary to its rationale – not lead to a deregulation but rather to a considerable tightening of the legal requirements for placing medical devices on the market (production and import) in Europe.

Legal Development in Germany

The hearing of the Federal Ministry of Health on the draft of the Third Amendment to the Medical Devices Act, an article law of little extent which is to amend the Medical Devices Act and several of its implementing ordinances, took place in September 2005. BVMed welcomes that the term "operator" is to be legally defi-

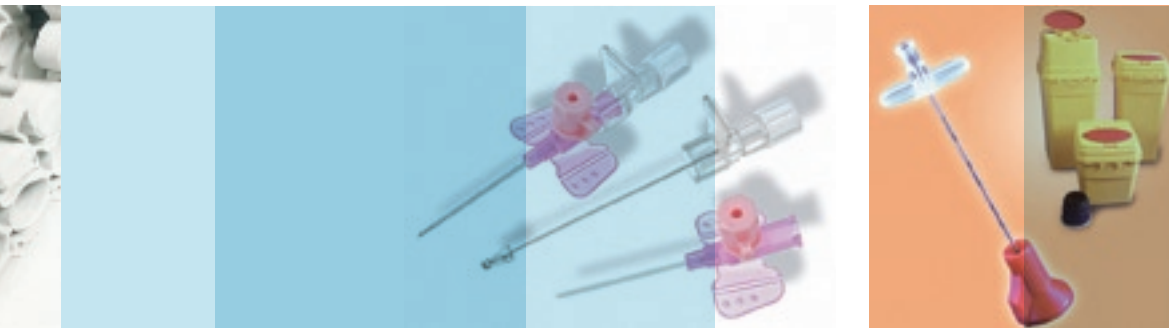
ned for the first time. According to reports, the health insurance funds are opposed to being held accountable as "operators" for the maintenance of their own medical devices and to covering the costs arising from it. The Fourth Amendment to the Medical Devices Act in 2007 will be much more interesting, as it will provide for the national implementation of the amended European directives 90/385/EEC and 93/42/EEC as well as for the implementation of directive 2005/50/EEC.

Law on Advertising in the Healthcare System

In August 2005, the prohibition of cash discounts and rebates in kind for medical device advertising purposes in § 7 of the Law on Advertising in the Healthcare System (Heilmittelwerbeengesetz – HWG) was relaxed. A more precise stipulation of the as yet undefined limitations of permitted discount advertising will be rendered by the upcoming jurisdiction. The legal regulations on the advertising for medical devices are illustrated in detail in the commentary on the Law on Advertising in the Healthcare System integrated in the "WiKo – Commentary on Medical Device Legislation".

Act on the Establishment of the German Drugs and Medical Devices Agency (DAMA)

The establishment of the new German Drugs and Medical Devices Agency (DAMA) in the fall of 2006 is aimed at increasing the efficiency of the present Federal Institute for Drugs and Medical Devices (BfArM). For this purpose, a comprehensive reorganization of the institute including personnel restructuring measures has been initiated. The new legislation on collective agreements for the public service, which came into effect in the fall of 2005, provides for the possibility of replacing civil servants with public employees who are paid according to their performance and whose employment contracts can be terminated by the public employer with due notice, which is to improve the new agency's performance. On the occasion of a hearing on the DAMA Establishment Act, BVMed successfully demanded that the term "medical devices" should once again become part of the name of the BfArM successor organization DAMA. The law's coming into effect has been delayed by the early Bundestag elections in the fall of 2005.



Prevention of Sharps Injuries by Use of Safety Products

Patient and User Safety/Environmental

Reuse of Medical Devices

If single-use medical devices are reprocessed, e.g. at the instigation of a hospital, and reused on another patient, the manufacturer assumes no liability for any consequential damages. As the device was designed and validated for single use only, there is no available information on the potential consequences of reprocessing and reusing medical devices contrary to the manufacturer's instructions. Therefore, liability for any resulting harm to patients rests with the operator and thus, in this case, with the hospital. Yet, the reuse of single-use devices is not prohibited and a rather common practice in Germany.

BVMed has been directing the attention of users and operators to this problem for many years. An information card published by BVMed provides advice on the legal consequences and information about 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 extent to which the quality and safety of single-use devices can be compromised by reprocessing practices that are contrary to the manufacturer's intended uses is demonstrated in conferences. Regular "Reuse News" provide information on current cases and international policies. In spite of all efforts, neither the draft of the Third Amendment to the Medical Devices Act nor the proposal for the review of the Medical Devices Ordinance provide for specific regulations for protecting patients from possible harm which may arise from the use of reprocessed single-use devices. After all, it can be assumed that the Amendment to the Medical Devices Act will make clear that facilities such as sickness funds or providers of medical supplies are also liable as operators of medical devices.

Prevention of Sharps Injuries

Improper handling is one of the causes for so-called sharps injuries which has particularly serious implications for healthcare personnel themselves. The number of sharps injuries sustained in Germany is estimated at 500,000 cases per year. Sharps injuries can result in illness, loss of job or occupational disability. For medical facilities, this means a temporary loss of their employees' services in patient care or even the loss of their em-

ployees. A technical guideline (TRBA 250) issued in 2003 therefore provides for a replacement of "sharp, pointed or fragile devices by such suitable devices or procedures that involve no or next to no risk of puncture or laceration wounds". BVMed's members offer a variety of devices which help reduce the risk of sharps injuries to a minimum if used according to instructions.

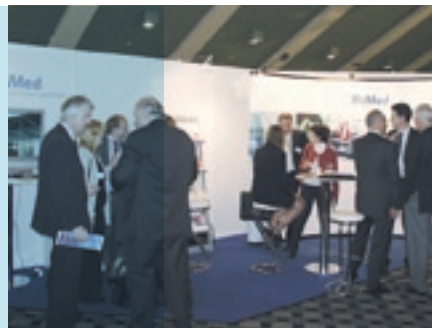
At BVMed's "Safety Symposium" in February 2005, representatives of hospitals, accident insurance funds and employers' liability insurance funds jointly looked into the question of "What has been achieved by the implementation of the technical guideline TRBA 250?" A study on the adoption of safety devices showed that no more injuries from pointed or sharp medical devices were recorded in areas where safety devices had been adopted.

Environmental Issues for the Medtech Companies

Since 24 November 2005, manufacturers of electric or electronic equipment have been obliged to be registered at the designated foundation "EAR Elektro-Altgeräte Register" ("WEEE register"). This also affects the manufacturers of medical devices, with the exception of implants and infectious devices. As of 24 March 2006, electronic equipment will have to be marked in accordance with the respective ElektroG provisions and producers will have to ensure that waste equipment can be returned by users. The rules on the implementation of the law are laid down in the so-called "rule book" of EAR. Specific rules for medical devices are stated in rule "03-008 Types of Equipment Medical Devices", in the compilation of which BVMed was actively involved. The European Commission's plans for a complete and radical review of the EU's chemicals policy which have become generally known by the abbreviation "REACH" will affect the medical technology companies as well. It is likely that well-established substances will become more expensive or even disappear from the market altogether. BVMed warned of this risk in its statements and called for an unconditional application of the principle of risk-benefit analysis for medical devices. For this remains valid: health protection must come before environmental protection.



BVMed Press Seminar in Berlin



BVMed Booth at Capital Congress in Berlin



Shooting for BVMed's TV Service

Communications/Press

The medically insured or the patients, respectively, are becoming an increasingly important target group for the Medtech sector's communication activities. This, in turn, has a considerable impact on communication tools and their language. Media work and PR are thus gaining in strategic significance for the companies. This development means: professional communication strategies must and will become more important for the medical technology companies. BVMed offers its support to all stakeholders by holding its annual Medtech Communications Congress. In 2006, the congress will take place as a two-day event for the first time (30 to 31 May 2006).

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 nine areas of medical technology – the most recent ones covering patient mobility and biotechnologies.

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 2005, Aktion Meditech reached 128 million readers via 150 articles in yellow press magazines. Further activities consisted of the second "Patient Group Symposium", a media seminar, four "decision-

maker events" for politicians 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. 2005's media tools were, among others, press releases, press conferences, articles and contributions for magazines as well as media cooperations. 110 million reader contacts were achieved with more than 600 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 June or the sixth BVMed press seminar in November 2005. BVMed is also actively involved in the image campaigns "Vitale Gesellschaft" (vital society – www.vitale-gesellschaft.de) of the federal association of German industry, BDI, and "Health First" (www.healthfirsteurope.org) of Eucomed.

Internet and Extranet

In 2005, BVMed's German and English internet pages at www.bvmed.de recorded more than 16.5 million hits in total, which stands for an increase of more than 80 per cent over the previous year. A total of 630,000 individual visitors accessed the association's websites. The average visiting time spent on the more than 5,000 individual internet pages of BVMed amounted to some five minutes. BVMed's extranet provides a central information and communication platform for all member companies.

8th E-Commerce Conference

With its so far 8th E-Commerce conference in February 2006 on electronic procurement, which was attended by some 230 participants, 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)

Among the key issues addressed by AKGS in 2005 were the Joint Federal Committee's code of procedure and the general elections. The group monitored the elections closely and worked out the so-called "Agenda for Innovation". BVMed's political positions were explicitly defined in the group's "9 theses on health economy 2005plus". These measures were supplemented by several events on the health economy and the innovations forum in the fall of 2005. For the first time, a joint congress on innovation was carried out in cooperation with the German health research and consultancy company IGES (Institut für Gesundheits- und Sozialforschung) and the sickness fund TK (Techniker Krankenkasse).

Focus Group "Legal Issues" (AKR)

AKR holds joint meetings with the members of the "Network Medical Devices", a group of presently nine specialized lawyers. The group addressed the legal issues brought to its attention by BVMed's board or expert committees, with particular regard to legislative initiatives. AKR is in charge of updating and editing BVMed's "WiKo-Commentary on Medical Device Legislation" (ISBN 3-504-04002-5). The latest WiKo supplement, which is to be published in April 2006, will provide a complete update of the included commentary on the

Law on Advertising in the Healthcare System and all legal texts as well as of the commentary on medical device legislation and the overview of the approximately 800 standards for medical devices.

Focus Group

"Regulatory and Public Affairs" (AKRP)

Key issues in 2005 were the answering of regulatory questions conveyed by BVMed's expert committees, member companies and the relevant authorities as well as the participation in and consultancy on the proposed amendment of European directives. The group furthermore updated the guidelines "Clinical Evaluation of Medical Devices" and "Market Surveillance of Medical Devices". AKRP is also in charge of organizing events on the "Consultation Process for Medical Devices Containing Pharmaceuticals", the "Practical Implementation of the Medical Devices Act" and on the "Clinical Evaluation of Medical Devices".

Focus Group "Environment" (AKU)

The main focus of this group in 2005 was on the Electric and Electronic Devices Act (ElektroG). AKU's sub-group "ElektroG" delegated two experts to participate in the preliminary product category group of the "EAR Elektro-Altgeräte Register", which supervises the rules on the implementation of the law. At an environmental workshop in February 2006, the second key issue next to the ElektroG was put up for discussion: the EU Chemicals Policy (REACH). In its statements on the previous draft legislation, BVMed had called for exceptions from the REACH requirements on the grounds that the medical devices directives already governed the requirements on safety and health and – unlike REACH – assigned the really important priorities for healthcare with the principle of benefit-risk analysis.

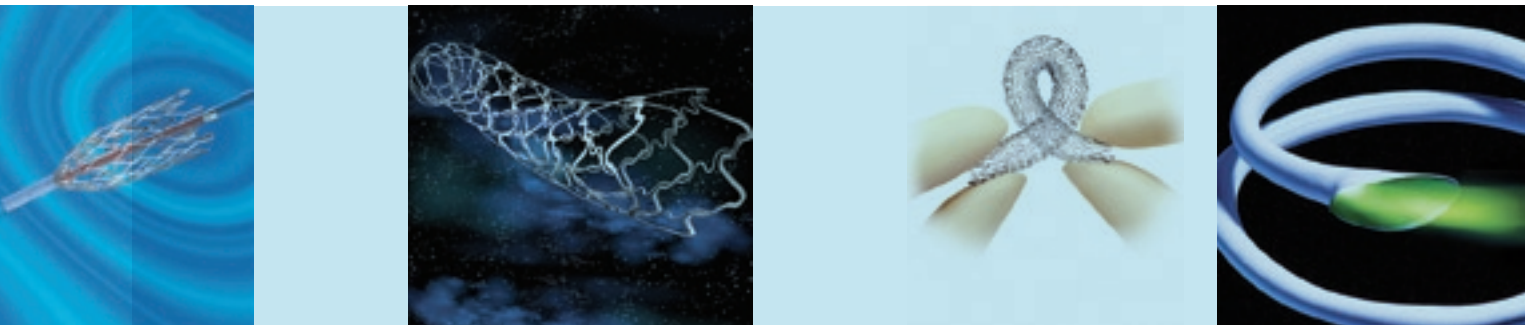
Focus Group

"Electronic Communication" (AKEKOM)

The automated labeling of devices by means of "Auto-ID systems" remains the most important issue for this focus group. In terms of usage, visual symbologies, that is to say, linear or two-dimensional bar codes, are still ahead of radio frequency identification (RFID) labels. This is also true for European and international

Focus Groups

- Electronic Communication in the Healthcare Market
- Environment
- Healthcare Systems
- Legal Issues
- Regulatory and Public Affairs



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

Sectoral Interest Groups

- Absorbing Incontinence Care (Manufacturers)
- Anti-Decubitus Aids
- Application Aids
- Artificial Feeding
- Bandages
- Blood
- Brachytherapy
- Cardiovascular Medical Devices
- Compression Stockings
- Ethylene Oxide Sterilization
- First Aid Materials
- Health Insurance Law for Care Providers
- Homecare
- Infusion Therapy
- Intraocular Lenses
- Medical Technology Implants
- Minimally Invasive Procedures
- Modern Wound Care Products
- ...

developments. In view of the large number of national special regulations imposed by authorities or customers, the most important objective is the standardization of requirements. The brochure “Bar Codes on Medical Devices” provided by AKEKOM’s sub-group “Bar Codes” is also available in English and is frequently used for assistance on this subject.

Sectoral Interest Groups

Sectoral Interest Group “Bandages” (FBB)

In agreement with the federal association of guild health insurance funds (IKK-Bundesverband) and the SHI funds’ medical review board, FBB and EUROCOM jointly prepared a draft for the machine-produced orthotics part of product group 23 “Orthotics/Splints” of the medical technical aids register. Further key issues were the reuse of orthotics and problems relating to value added tax.

Sectoral Interest Group “Blood” (FB Blood)

The group dealt with considerations of environmental associations and authorities of withdrawing well-established and hitherto irreplaceable materials from the market in anticipation of the planned European legislation on chemicals. FB Blood was also actively involved in the preparation of a general survey of products and materials for the German Federal Institute for Drugs and Medical Devices (BfArM) and thus made its mark as a precursor for the activities of the working group PVC (PG PVC).

Sectoral Interest Group “Brachytherapy” (FBBT)

FBBT’s working group “Interstitial Brachytherapy” (PG IBT, Seed method) promotes the adoption of this gentle form of therapy in outpatient care. The group monitors the Joint Federal Committee’s assessment procedure as well as the evaluation of this therapy by the IQWiG. Furthermore, an HTA report on this therapy published by the national association of SHI physicians and the German Medical Association was supported with statements.

Sectoral Interest Group “First Aid Materials” (FBEH)

This sectoral interest group, which represents the manufacturers of office and car first aid kits, mainly concerned itself with the acceptance and applicability of innovations relating to the “classic” first aid kit. Standardization work in first aid is of major importance for FBEH. The group has been increasingly addressing infection prophylaxis issues and threats posed by natural disasters and major emergencies. FBEH’s sub-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 “Anti-Decubitus Aids” (FBHD)

The members of this group actively participated in the updating process of product group 11 “Anti-Decubitus Aids” of the medical technical aids register with an expert statement and involvement in discussions with the SHI funds’ medical review board and national associations. Thus, the group was able to prevent that proof of therapeutic benefit must be exclusively determined by studies of evidence level 1. Furthermore, the group expressed its commitment to securing an individual and patient-oriented care with decubitus aids to all partners on the decubitus market. Uniform quality standards and the recently compiled brochure on “Selecting the right anti-decubitus aid” will help achieving this objective.

Sectoral Interest Group “Homecare” (FBHC)

FBHC compiles information on new forms of care and supports the European umbrella association EUCOMED in its work. In order to accommodate the particular interests of the trade companies represented by BVMed, a separate platform for political opinion-forming and the determination of strategic health political positions and activities of the trade companies was established. 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.



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

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)

FBIOL was intensely engaged in the preparation of a new reimbursement model for intraocular lenses. Along the lines of BVMed’s “Delta Financing Model”, this model 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. A sub-group supports the conceptual and technical design of the model and prepares the ground for discussions with doctors and health insurance funds. Further issues of this sectoral interest group were the cooperation with ophthalmologists, quality assurance and data management in doctors’ offices as well as active involvement in trade fairs and conferences in the field of ophthalmology.

Sectoral Interest Group “Cardiovascular Medical Devices” (FBKMP)

This group’s objective is to ensure appropriate reimbursement for innovative cardiovascular medical devices in both inpatient and outpatient care. Its activities also comprised regular contacts to the relevant medical expert societies and professional associations, which were cultivated in symposia and regular meetings. The group also supported so-called “cost model studies” on active implants in cardiology.

Sectoral Interest Group “Artificial Feeding” (FBKE)

The revision of the pharmaceutical guideline on the reimbursement of oral supplement and tube feeding represented the main focus of this sectoral interest group. BVMed and other affected associations success-

fully identified the difficulties and inadequacies of the draft presented by the Joint Federal Committee. In consequence, the Federal Ministry of Health objected to the draft for the third time and issued an executive fiat, which came into effect on 1 October 2005. The provisions stipulated by the Ministry will remain in effect until reviewed by the Cologne Social Court. BVMed has published a flyer summarizing these provisions.

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, or the contract drafting and formation between nursing homes and long-term care insurance funds. The group’s newsletter “Blick. Sozialrecht” (in focus: social legislation) provides the basis for a regular exchange of information. A working group of FBLL is concerned with all matters pertaining to the electronic health card and the so-called e-prescription. The working group prepared a proposal for the assignment of health professional cards.

Sectoral Interest Group “Medical Technology Implants” (FBMTI)

This sectoral interest group evaluates DRGs which are of particular significance for endoprosthetics and their impact on the endoprosthetics industry. Further key issues were the analysis of developments in health policy with a view to the implants sector, congress management, activities of the campaign “Orthopädie bewegt” (Orthopedics move) as well as the introduction of a German endoprostheses register.

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

The most important topic for this group was the prescribability and reimbursability of dressing materials, and of modern wound care products in particular. There is still a great need for information and education

- ...
- Ostomy/
Incontinence Care
- Peripheral Vascular
Medicine
- Practice Supplies,
Prescribable
Supplies,
Medical Dressings
- Radiation
Sterilization
- Spine Surgery
- Supply of
Sterile Goods
- Therapeutic
Apheresis
- Tracheostomy/
Laryngectomy



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



Ceramic Implants



Ankle Joint Prosthesis

in prescribers as well as in health insurance funds. Thus, FBMW prepared a dressing material section for the so-called “Yellow List” and organizes informative events on “Hydroactive Wound Care”. One further tool of information is represented by the group’s brochure on the prescribability and reimbursability of hydro-active wound care products, which is updated on an annual basis.

Sectoral Interest Group “Peripheral Vascular Medicine” (FBPG)

The main focus of FBPG’s work is on ensuring that medical technologies are properly represented in the German DRG system and on establishing a scientific register for the recording and post surgical observation of patients suffering from peripheral occlusive arterial disease before or after undergoing PTA. The register is evaluated by three participating medical expert societies.

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

One of the key issues of this group is the maintenance of the quality of care at cost-covering reimbursement rates. With this in mind, FBI also explores alternative reimbursement schemes.

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 introduction of the new reimbursement catalog “EBM2000plus” and its potential impact on material costs due to the intended implementation of a new section on material costs remained in the focus 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). The sub-group “Supply

of Sterile Products” (AGSV) is concerned with the convergence of European and international standards for sterile product packaging. Questions relating to the handling of potentially contaminated returned medical devices are addressed by the sub-group “Returns” (AGR). The sub-group “Catheters” (AG KATH) provides a forum for users and authorities seeking particular information on catheters.

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

The group continued its PR activities on the maintenance of the quality of ostomy and incontinence care under the umbrella of the “Ostomy-Incontinence Forum” (Forum Stoma-Inkontinenz – FSI), which had already been established in 2004. FBSI’s work was also marked by hearings on the updating and assignment of reference price groups for draining incontinence products. The group’s statements contributed to the grouping of incontinence products according to similarity and equal value in function.

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. FBTA is committed to improving the available data in this area.

Sectoral Interest Group “Tracheostomy/Laryngectomy” (FBTL)

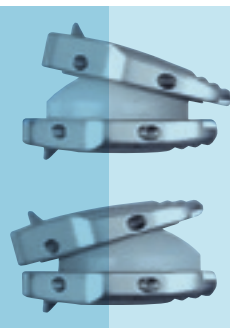
FBTL prepared a statement on the update of product group 12 “Technical Aids for Tracheostomy” of the medical technical aids register. The group is also committed to maintaining the individual care of tracheotomized and laryngectomized patients, particularly in outpatient care. Further issues are billing and co-payment problems as well as the reuse of suction devices. The group prepared a guideline on the care of tracheotomized and laryngectomized patients which is to contribute to quality assurance.



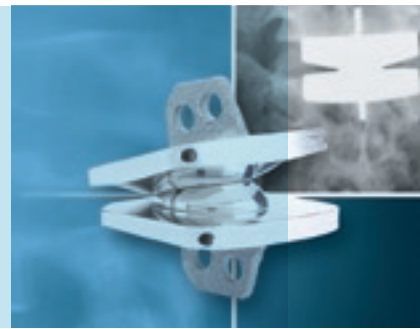
Artificial Knee Joint



Artificial Shoulder Joint



Intervertebral Disk Implants



Sectoral Interest Group “Spine Surgery” (FBSC)

The group submitted proposals for the appropriate reflection of various medical technology procedures on the spine in the DRG system. FBSC is also engaged in the development of a coding guideline in cooperation with the participating medical expert societies.

Working Groups and Sub-Groups

Working group “Reuse” (PG Reuse)

Contributions at MedInform’s conference on the “Reuse of Medical Devices” in October 2005 illustrated the fact that the reprocessing practice can have major implications for the quality of products and thus for patient safety. Therefore, PG Reuse will reinforce its cooperation with patient associations. Since the insufficient reprocessing of multiple-use medical devices can also have serious consequences, the working group “Suction Devices” will continue its activities. The group distributed its guideline on the “Reprocessing of Suction Devices” among providers of medical supplies and sickness funds and urged them to comply with the quality requirements.

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 according to § 115 b of the German Social Code, Book Five. For instance, the group was able to accomplish the integration of technologies for pain therapy into the service catalog.

Working Group “Sets” (PGS)

The group continued its PR activities on the value of using catheter sets and on the necessity of uniform SHI reimbursability in office-based outpatient care. A flyer and an internet brochure of the group provide all interested parties with information on the use of catheter sets.

Working Group “Tissues” (PGT)

PGT devoted particular attention to the publication of the draft proposal for a European regulatory frame-

work on “advanced therapies”, which seeks to harmonize the member states’ heterogeneous requirements on tissue engineering. Contrary to the medtech companies’ proposals, elements of this draft proposal strongly approximate the regulations for pharmaceuticals.

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) for this technology.

Sub-Group “Sharps Injuries” (AG NSV)

The manufacturers of safety devices within this working group demonstrated their commitment to a consistent implementation of existing laws and regulations on the prevention of sharps injuries with a variety of measures. In order to improve the continuously inadequate data available, study projects were supported and existing data on the application of instruments was made available. Contacts to nurse training facilities were intensified and the networking with other European initiatives was stepped up.

Sub-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. In 2005, two fields of interest were at the top of the group’s agenda: the monitoring and legal evaluation of the health insurance funds’ tendering procedures as well as the revision of the pharmaceutical guideline on the reimbursability of oral supplement and tube feeding. The regular meetings of the so-called “Social Legislation Network” with external lawyers, representatives of the Federal Ministry of Health and judges of the social courts have received a positive response.

Working Groups

- Chronic Wound
- Electrostimulators
- Guideline Innovative Medical Devices
- Intermittent Catheterization
- Interstitial Brachytherapy
- Material Costs and Outpatient Surgery
- Natural Latex
- PVC
- Reuse
- Sets
- Surgical Fabrics
- Tissues
- VAD/Artificial Heart



BVMed's Head Office in Berlin



BVMed's Annual Meetings with Foreign Minister and former Head of the Chancellery Dr. Steinmeier and Health Economist Dr. Fritz Beske



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Director General BVMed

Director General

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BVMed in Dialog: with Health Minister Ulla Schmidt and IQWiG Director Professor Dr. Peter Sawicki

BVMed – Our Services for You

BVMed represents some 210 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 implant 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 sqq. 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:

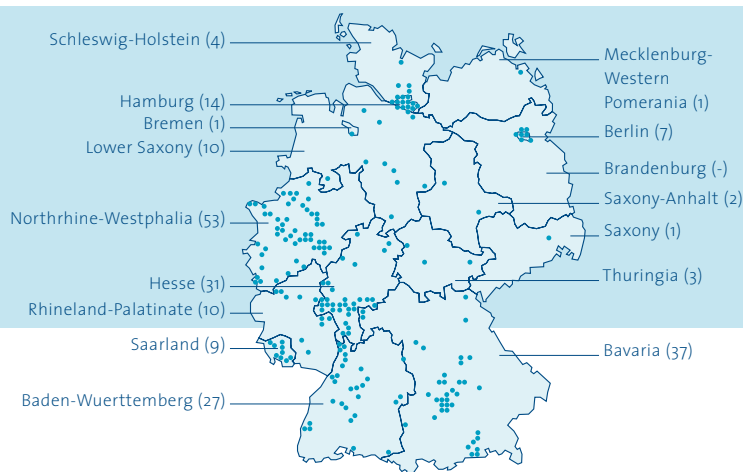
- :: Political marketing
- :: Individual policy talks
- :: Maintenance and support of networks
- :: Parliamentary evenings
- :: Background talks
- :: Participation in parliamentary hearings
- :: Representation in committees, boards of trustees, commissions, etc.

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 can 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 on 1 March 2006: 210 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 Vascular Devices
ABENA Hygiene GmbH
ABIOMED BV
Acri.Tec Gesellschaft für ophthalmologische Produkte mbH
ACRIMED GmbH
Adexter GmbH
ADL Anti Dekubitus Lagerungssysteme GmbH
*AESULAP AG & CO. KG
AirMed Prophylaxe + Therapie Systeme GmbH
AirSystems Medizinische Produkte GmbH
ALCON Pharma GmbH
American Medical Systems Deutschland GmbH
*AMO Germany GmbH
AMOENA Medizin-Orthopädie-Technik GmbH
Andreas Fahl Medizintechnik-Vertrieb GmbH
Ansell GmbH
ARROW Deutschland GmbH
ASSIST Heimpflege-Bedarf GmbH
Astra Tech GmbH
ATMOS MedizinTechnik GmbH & Co. KG
Atos Medical GmbH
AURELIA Medical Handel GmbH

B

B + P Beatmungsprodukte GmbH
*B. Braun Melsungen AG
*Bausch & Lomb 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. KG
*Boston Scientific Medizintechnik GmbH
*Bristol-Myers Squibb GmbH & Co KGaA
ConvaTec Vertriebs GmbH
*BSN medical GmbH & Co. KG
BSN-JOBST GmbH

C

*C.R. Bard GmbH
Cardinal Health Germany 206 GmbH
*CeramTec AG
Chemische Fabrik Kreussler + Co. GmbH
Clinical House GmbH
Clinico Medical Production GmbH
*Coloplast GmbH
Coltène/Whaledent GmbH + Co. KG
Cook Deutschland GmbH
*Cordis Medizinische Apparate GmbH
*Corin Germany GmbH
CORNEAL GmbH Medizinische Optik
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
Dr. Ausbüttel & Co. GmbH Verbandstoffe
und Medicalprodukte

E

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

F

FOR LIFE Produktions- und Vertriebs-
gesellschaft für Heil- und Hilfsmittel mbH
Franz Kalff GmbH
*FRESENIUS AG
Fritz Oskar Michallik GmbH & Co.
Fuhrmann Verbandstoffe GmbH

G

GAMBRO Dialysatoren GmbH
GANZONI GmbH
GARANTOL Products Detia Freyberg GmbH
GE Medical Systems Accessories & Supplies
GmbH
Genzyme GmbH
*GerroMed Pflege- und Medizintechnik
GmbH & Co. KG
Given Imaging GmbH European Headquarters
GUIDANT GmbH

H

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

I

IIP-Technologies GmbH
Impella CardioSystems AG
INAMED Aesthetics GmbH
INVATECH Gesellschaft für fortschrittliche
Medizintechnik mbH & Co. KG
Isotron Deutschland GmbH

K

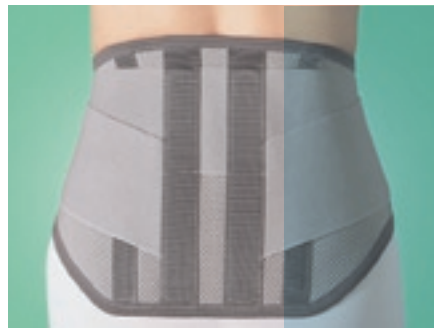
Kaneka Pharma Europe N.V. German Branch
Karl Beese (GmbH & Co.)
Karl Otto Braun KG
KCI Therapie-Geräte GmbH
Keimed GmbH (HSC)
Kettenbach GmbH & Co. KG
KLUGE medical Gesellschaft für
Hygiene und Medicalprodukte mbH
*KRAUTH medical KG (GmbH & Co.)
Kyphon Deutschland GmbH

L

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

M

Maco Pharma International GmbH
Maimed Medical GmbH & Co. KG
MAQUET Cardiopulmonary AG



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

MATHYS Orthopädie GmbH
 medac GmbH Gesellschaft für klinische
 Spezialpräparate
 Medex GmbH
 *medi Bayreuth GmbH & Co. KG
 medinone medical großhandels gmbh
 Medical Service GmbH
 *Medi-Globe GmbH
 mediLog Handelsgesellschaft mbH
 MEDTHODIC Bernd A. Harren KG
 *Medtronic GmbH
 megro GmbH & Co. KG Medizintechnischer
 Großhandel
 Mentor Deutschland GmbH
 nepro Medizinische Produktion GmbH
 Merete Medical GmbH
 *Mölnlycke Health Care GmbH
 Mundipharma GmbH

N
 Nestlé Nutrition GmbH
 neurotech Bio-Medical Research GmbH
 NOBA Verbandmittel Danz GmbH & Co. KG
 Noma med Schütze / Schuster GbR
 Novartis Nutrition GmbH
 Novo Klinik-Service GmbH

O
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 Otto Bock HealthCare GmbH

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 Pall GmbH Medical
 PAPER-PAK GERMANY GmbH
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 PAUL HARTMANN AG
 Peter Brehm GmbH Chirurgie-Mechanik
 *pfm Produkte für die Medizin AG
 Pfrimmer Nutricia GmbH
 PHADIMED GmbH & Co. KG
 PlasmaSelect AG
 *Plus Orthopedics GmbH
 PMT Präzision-Medizin-Technik GmbH

POLYTECH Ophthalmologie GmbH
 *POLYTECH-SILIMED Europe GmbH
 PULSION Medical Systems AG
 *pvb Critical Care GmbH

Q
 Q-MED GmbH

R
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 Raguse Gesellschaft für medizinische
 Produkte mbH
 *Raumedic AG
 Regent Medical Overseas Ltd.
 Zweigstelle Deutschland
 rehaVital Gesundheitsservice GmbH
 Rentex Vertriebs GmbH
 Resorba Clinicare GmbH
 *RUTH CEGLA GmbH & Co. KG
 Medizinisch-Technische Geräte

S
 SANDER Chemisch- Pharmazeutische
 Fabrik GmbH
 sangro medical service GmbH
 *Sanicare GmbH
 Sanitätshaus Aktuell AG/EGOS
 SCA Hygiene Products GmbH
 Incontinence Care
 Sengewald Klinikprodukte GmbH & Co. KG
 *servoprax GmbH
 SERVOX AG
 SFM Süddeutsche Feinmechanik GmbH
 Signus Medizintechnik GmbH
 *Smith & Nephew GmbH
 *Smiths Medical Deutschland GmbH
 Sorin Group Deutschland GmbH
 Spring Medical Wilhelm Spring GmbH & Co. KG
 St. Jude Medical GmbH
 Sterigenics Germany GmbH
 Steritex KG Schneeweiß 1882 GmbH + Co.
 Stryker GmbH & Co. KG
 SYNTHES GmbH
 System France System Assistance Medical

T
 *TECHNOMED Gesellschaft für med. und
 med.-techn. Systeme mbH
 Teleflex Medical GmbH
 TERUMOX (DEUTSCHLAND) GmbH

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 *Thomas Hilfen für Körperbehinderte
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 Tutogen Medical GmbH
 *Tyco Healthcare Deutschland GmbH
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U
 UDO HEISIG GmbH The Disposables Company
 *URGO GmbH
 URSAPHARM Arzneimittel GmbH & Co. KG

V
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 Veritas Medizintechnik GmbH
 Vitatron GmbH
 VYGON GmbH & Co. KG

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 applications are located on the internet at
www.bvmed.de (Pictures).

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