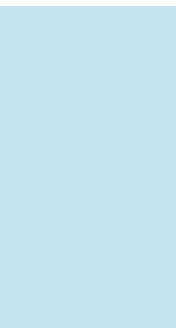


The Medical Technology Companies

∴ ∴ ∴ ∴ **BVMed**
Enhancing Health.



Annual Report 2007/08



Medical technologies are indispensable for people's health and quality of life:
They save life and promote healing – in every stage of life

Content

Content

- 3 Introduction
New Alliances for Medical Progress and Quality
- 4 BVMed's Market and Membership Development

Domestic Conditions

- 5 Industry Report Medtech 2007 / 08
- 6 Good Domestic Conditions for the Medtech Sector:
What Needs to be Done?
- 7 Health Policy

Particular Subject Areas

- 8 German DRG Hospital Financing
- 9 Health Technology Assessment (HTA)
- 10 Technical Aids
- 11 Homecare
- 12 Medical Device Legislation
- 13 Patient and User Safety / Environmental Issues
- 14 Communications / Press

15–19 Reports from BVMed's Expert Committees

Service

- 20 BVMed – At Your Service!
Board and Head Office
- 21 BVMed – Our Services for You
- 22–23 Member Companies

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Dr. Meinrad Lugan
Chairman of the Board of BVMed

Introduction

New Alliances for Medical Progress and Quality

The world of medical technologies is fascinating. Implantable medical devices cause the heart to beat rhythmically again. They make it possible for joints to move without pain, eyes to see and ears to hear. Neurostimulation gives chronically suffering patients new hope in treating a wide range of diverse syndromes. New procedures, implants, single-use devices or technical aids improve the quality of life and even frequently save and preserve life. Nowadays, the treatment of many diseases is scarcely conceivable without the use of modern medical technologies.

Dealing with medical technology advances is one of the most important formative issues in the healthcare market. It most especially concerns the medical technology companies as part of a dynamic and highly innovative industry. The fact is that German medical technology manufacturers achieve a good third of their business volume with products which are less than three years old. The researching companies in the Medtech sector invest an average of about nine percent of their sales revenues in research and development.

For BVMed and medical technology companies, it remains a great challenge to convince decision makers with the help of studies and clear lines of arguments that innovations in the healthcare market should not only be debated with respect to cost aspects. We want to work towards having not only the usually higher initial costs of a new procedure considered in isolation, but rather to get the entire costs of a treatment case assessed and evaluated. To do so, we need an improved data basis on the use of medical technologies under "everyday conditions" in clinical practice as well as the doctor's office.

We try to solicit new alliances for quality and medical advances in the healthcare market. We need better cooperation between policymakers, health insurance funds, hospitals, physicians and industry in order to ensure high quality Medtech care for people and to see that innovations and medical progress reach the patients fast.

BVMed exerts itself on behalf of joint projects between companies in the Medtech sector and the health insurance funds and physicians in order to develop and stipulate criteria for a genuine quality competition. The common objective on behalf of the patient must be to counteract the trend towards cheap medicine. A positive example is the set of quality standards governing the supply of technical aids. We also need more projects in hospital care to make quality measurable.

BVMed and the medical technology companies offer their experience and expertise as constructive partners and co-shapers for this important process.

Best regards

Dr. Meinrad Lugan
Chairman of the Board of BVMed



The highest standards apply for the production and quality control of medical devices – whether hightech or textile processing

BVMed's Market and Membership Development

Membership Development

Presently (in March 2008), some 204 industry and trade companies are represented by BVMed. After a year of numerous takeovers and mergers, that number is two companies less than a year ago. Please find a complete list of BVMed's members on pages 22/23. In 2006, 8 companies joined BVMed. At the beginning of 2007, one further company became a member of the association. On the other side of the scales, there were nine leavings as well as three mergers in 2007.

Market Development

As a whole, the mood in the Medtech industry has been distinctly better in 2007 than in 2006, when less satisfactory results were achieved by medical technology companies due to the physicians' strike, sustained downward pressure on prices in the hospital sector and the insecurity caused by the healthcare reform. In 2007, an average sales revenue development of 4.6 percent paints a rosier picture. The extremely broad spread among the various product areas must be taken into consideration. While staple products showed stagnation or even a decline in sales, some innovative sectors were able to produce double-digit growth rates.

Results of the Membership Survey

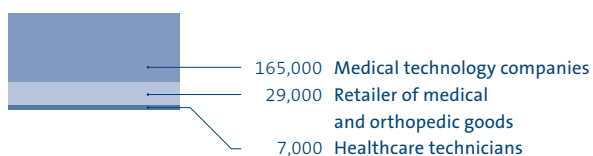
A current industry survey conducted by BVMed, in which 140 member companies (66 percent) participated, yielded the following most significant results:

- :: The Medtech companies organized in the BVMed invest an average of about nine percent of their sales revenues in research and development.
- :: The sector's innovative capability is reflected in the fact that almost 80 percent of the companies plan to launch new products and methods on the market in 2008. As expected, most innovations affect the hospital sector.
- :: About 55 percent of the companies have created new jobs in 2007, of these eight percent considerably more jobs. The new employment values of previous years of 46 percent (in 2006) and 36 percent (in 2005) were thus clearly exceeded. The Medtech sector remains a job motor.
- :: When asked whether Germany provides a good environment for medical technology industry, the BVMed companies decidedly express approval and strong appreciation. The main factors cited were the large number of well-trained physicians (55 percent), the high level of medical care of patients (54 percent) as well as the high standards in clinical research (38 percent). The quick marketing authorization is mentioned by 37 percent as a strength, 36 percent cite the well-trained scientists.
- :: The primary criticism centers on the low level of reimbursement in Germany compared to other European countries. This particularly applies to the implant sector, where the lowest prices are to be found in Germany.
- :: The strongest obstacle for the development of the sector is considered to be the increased downward pressure on prices by the buying cooperatives. 70 percent cite this factor, compared to 78 percent in the previous year.
- :: Above all, the BVMed companies want public health policy to provide more flexibility in the reimbursement systems. 61 percent advocate more individual responsibility on the part of the patients via co-payment schemes. 50 percent want more freedom of choice for the medically insured. The proposal of an outcome-oriented remuneration of healthcare services follows with 36 percent. 34 percent support the model „basic care plus supplementary insurance“ and 32 percent the decoupling of contributions from the labor costs.

Healthcare Expenses on Medical Devices
21 billion Euros



Jobs in the German Medical Technology Industry
a total of 201,000





(from left to right) Production of cardiopulmonary bypass machines, dialysis components and compression hosiery; quality control of hip shafts and incontinence products; packaging solution in the cleanroom

Industry Report Medtech 2007/08

Growth Market Health Economy

The health economy is already one of the most important and biggest market segments of the German economy today. A total of 4.3 million people are employed in health-care. Thus, almost every ninth job in Germany is based in the health economy. 240 billion Euros in total are annually spent on health. This represents a share of 10.7 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).

Expenditure for Medical Devices in Germany

Healthcare spending in the medical devices sector (without capital goods) in Germany amounted to more than 21 billion euros. Of this amount, about 10.5 billion euros account for medical technical aids, 9.5 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 amounted to some 14 billion euros.

Jobs

The medical technology industry employs 90,000 people in about 1,200 companies (with more than 20 employees per company). In addition, there are roughly 10,000 small businesses working in the sector with about 75,000 employees. The core industry thus employs some 165,000 people in Germany in more than 11,000 companies. Approximately 15 percent of the employees work in Research and Development (R&D), with a trend towards continued increase. Apart from a few large companies, the industry is strongly dominated by medium-sized firms. 95 percent of the companies employ fewer than 250 people.

Production and Export

The total business volume of manufacturing medical technology companies increased in Germany by 8.1 percent to 15.9 billion euros in 2006. The domestic sales volume rose by 3.2 percent to 5.7 billion euros, the export sales by 11.1 percent to 10.2 billion euros. 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).

Worldwide Growth Market of Medical Technologies

The medical technology industry is a worldwide growth market. Advances in medical technology, the demographic development with always more older people and the expanded idea of health will ensure that this remains the case. The demand for healthcare services will continue to rise. Patients are increasingly prepared to invest in their health.

In 2006 the world market for medical technologies amounted to about 200 billion euros. After the USA at 85 billion euros, the European market at 60 billion euros is the second largest market in the world. Besides the USA and Japan (25 billion euros), Germany is the third biggest market worldwide at 21 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 markets.

Outstanding Innovative Capability

The medical technology industry is dynamic and highly innovative. Germany ranks second place behind the USA in its share of patents and worldwide commerce. The German medical technology manufacturers achieve approximately a third of their business volume with products which are less than three years old. The researching companies in the Medtech sector invest an average of about nine percent of their sales revenues in research and development. Germany as a venue for innovation and research thus plays a particularly important role for the Medtech companies.

Another proof of the industry's high innovation capability: according to the European Patent Office in Munich, medical technology heads the list of registered inventions with over 15,700 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).

Applications to the European Patent Office in the year 2006

Medical Technology	15,752
Electronic Communications	13,488
Data processing	8,969
Electrical elements	8,062
Organic Chemistry	7,431
Measurement and testing tech.	7,151
Automotive engineering	4,322
Biochemistry / Genetic engin.	3,847
Macromolecular components	3,709
Machine elements	3,298

Medtech "top" in patent applications



The Medtech companies invest an average 9 percent of their sales volume in research and development

Good Domestic Conditions for the Medtech Sector: What Needs to be Done?

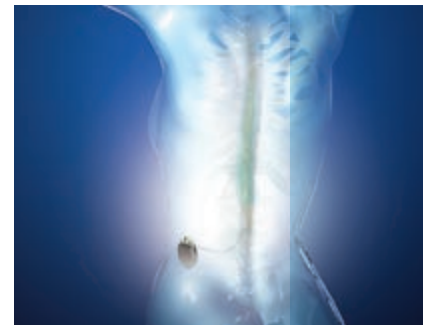
How can Germany's leading market position in medical technology be preserved and expanded in the long-term? How can general conditions be shaped to promote the Medtech industry? BVMed summarizes its appeal to policy-makers and the self-governing bodies in five different subject areas:

- :: We need a closer relationship between the political spheres of economy, research, finance and health in order to coordinate the cooperation of all responsible ministries for the health economy more effectively, especially on behalf of studies and support programs.
- :: We need to think more strongly in terms of processes in the health economy. We must consider an entire case, not isolated product costs. We are disturbed that innovations are often only discussed with regard to cost considerations. That point of view is too short-term. It is misleading to look at the usually higher initial costs of a new method in isolation. Therefore we have to work with the hospitals and users to develop instruments for determining the benefits and costs over the full length of a particular treatment or disease. The faster adoption of innovations also usually offers economic advantages as well by leading to a reduction of sick days, shortening patients' recovery times and thus enabling people to return to their social activities and their jobs more quickly.
- :: For the innovation capability of hospitals and the Medtech sector, it is important to preserve the principle of "permission with the reservation of prohibition". 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 must be adhered to in the inpatient sector, so that innovative medical technologies can be made available to all patients who require them without delay. The subject of promoting innovation also includes our revising and simplifying the so-called innovation clause for hospitals to introduce new Medtech sector procedures.

- :: An accelerated introduction of innovations is of great importance. For this we need more flexible reimbursement schemes. These include flexible co-payment schemes or the permission to self-insure. If we open up the system here, then the health insurance funds will compete for the rapid introduction of innovations in the future. This range of topics also includes simple process measures, such as those customary in industry. We must define unambiguous contact persons, procedures, deadlines and evaluation procedures for processes like the assessment of procedures or the revision of the DRG catalog. With clear definitions, we have a chance of accelerating the processes as a whole.
- :: A particularly sensitive sector is the supply of technical aids. Here the healthcare reform has brought about a fundamental change in the supply structures. In the future, those entitled to care must be contract partners of the health insurance funds, which will usually be determined by competitive bidding. Legal clarification is urgently required to establish that health insurance funds are public contract parties and that the invitations to tender constitute public orders. Invitations to tender are not the adequate means for supplying technical aids which require customized manufacture or adjustment or which involve a high portion of service; another solution is needed for providing optimized, high-quality care of extremely sick persons who cannot do for themselves, or chronically ill patients.

The upshot of these five subject areas:

If we promote innovations and proceed in a more coordinated manner, while taking greater consideration of quality aspects, then the Medtech companies will remain a growth engine of the health economy for the benefit of patients in the future.



New methods in cancer therapy (therapeutic device) and pain therapy (spinal cord stimulation)

Health Policy

Implementing the healthcare reform

The beginning of 2007 was characterized by the final negotiations to the so-called law for strengthening competition in social health insurance (SHI). To a large extent, this law became effective on April 1, 2007. Controversial parts of the law, such as the compulsory insurance coverage or the “health pool”, only come into effect later. One can detect a general tendency to postpone controversial or unpopular decisions to several years in the future. Policymakers can thus counteract criticism in the current discussion by referring to long transition periods. When the law eventually does go into effect, later generations can release themselves from responsibility by claiming they didn't participate in its making. With this in mind, the challenge for our association is to communicate feared consequences as well as to monitor the laws. It is necessary to conduct a continuous dialog with the political decision makers, often over the course of several years, concerning the actual specific consequences of legal provisions. An example of this is the revised regulations for invitations to tender in the medical technical aids sector, where BVMed regularly explains the impacts of such revisions to politicians and ministries and stresses the need for change.

Demand for a case-based expert in the Joint Federal Committee

Further new provisions of the healthcare reform become effective in mid-2008. These include the creation of a Central Federal Association of the Health Insurance Funds and the restructuring of the Joint Federal Committee (JFC). The fact that the meetings of the decision-making committee of the JFC will be open to the public in the future is considered an improvement. Furthermore, BVMed has appealed to the JFC for a change in the procedural standing orders and proposed that a case-based medical expert designated by the respective affected industry should take part in all JFC meetings in the future as an advisor without voting rights.

Current Legislation

- :: Apart from new stipulations concerning medical devices, the 3rd amendment to the Medical Devices Act [MPG] contains provisions governing the reimbursability of so-called drug-similar medical products (e. g. rinsing solutions or certain gels) as defined in § 31 Social Security Code Book V. In the past, this point has given rise to frequent ambiguities in the Statutory Health Insurance concerning reimbursability. The JFC is now to list the reimbursable products in a guideline.
- :: At the end of 2007, the German federal states agreed upon the blueprint for a regulatory framework for the hospital sector. The blueprint states that they want to retain the competence for hospital planning in the future. A cautious upgrading of the existing system is planned. Selective contracts should only be possible in exceptional cases, once the quality parameters have been previously specified. BVMed accompanied the whole procedure intensively with position statements and discussions in the different federal states. The legislative process is scheduled for 2008.

Further Activities of BVMed in Health Policy

The existing dialog with the political decision makers was further intensified in 2007. By means of good and regular contacts to the German Bundestag, Kanzleramt (Office of the Federal Chancellor), ministries, state representatives and experts BVMed is able to contribute its expertise and represent the interests of the industry in the current legislative process. The issues relevant to BVMed and its member companies are regularly debated in political discussion groups. While the health sector is most important, we also pursue other fields such as research and economic policy. BVMed advocates making better use of synergies between the policymakers of these sectors.



Medical devices for high-quality care in the sensitive surgery sector: safe, reliable, sterile

German DRG Hospital Financing

Discussion on the regulatory framework as of 2009

The discussion on the regulatory elaboration of financing hospital care as of 2009 is in full force. A majority of the federal states have agreed on their concept for further development of hospital care with special focus on financial aspects. This decision is of great importance, since the lawmakers cannot pass the future general legal framework in Germany without the approval of the federal states.

The federal states want to retain their healthcare mandate and design planning competence. They profess to the obligation to contract and to overcoming the sectoral separation between the outpatient and inpatient sectors. Furthermore, the states support a fixed price system. The price system should be dependent on quality criteria still to be developed. A nation-wide average case value should be aspired for the future. There is a clear rejection of a monistic solution. The present mode of budget cuts is seen as no longer appropriate.

From the viewpoint of BVMed, the decision of the federal states can be considered a reasonable approach to finding a solution combining high-quality care with medical technologies.

Little accordance between the German federal government and the states

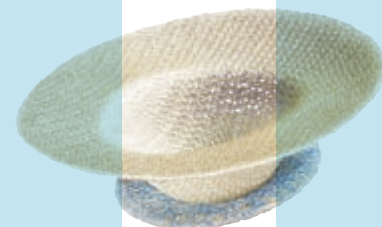
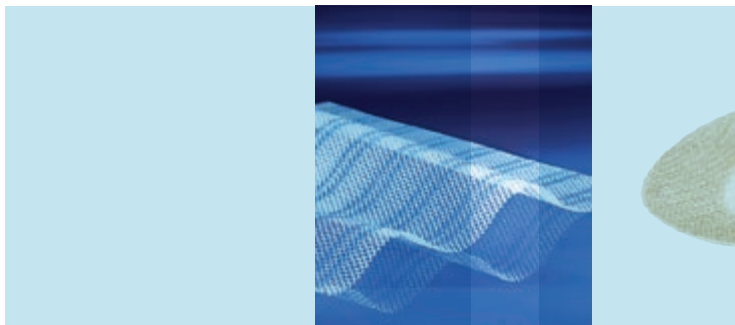
The German Federal Ministry of Health (BMG) wants a standard nation-wide definition and pricing of the DRGs. The state-wide average case values are to be replaced by one nation-wide average case value within ten years. In principle, there should be collective agreements on the hospital budget. However, the BMG advocates price competition for a predefined catalog of plannable and highly standardizable services. This should take place through contracts with individual health insurance funds based on maximum prices. Medtech procedures such as hernia surgery, cataract-surgery, endoprosthesis and cardiac pacemaker implants could be eligible for such a catalog. The patient should retain his freedom of choice. If he wants to choose something other than a "contract hospital", the hospital could bill its services according to the valid state-wide average case value.

Interim summary on the DRG system

BVMed is actively accompanying the discussion on the future of hospital financing. In its response to the BMG questionnaire, BVMed notes that 12 percent of the cost allocation in the DRG system is accounted for by implants and medical supplies including medical devices. The objective representation of medical technologies in the DRG system is of special importance for the future strength and acceptance of the system. Standard medical technology processes are generally integrated in the DRG system. However, innovative and new procedures are frequently inadequately represented, since these must first undergo time-consuming documentation and calculation, involving a delay of up to four years before being entered into the system. Also the current innovation clause which was supposed to bridge this gap has not proven helpful in practical application, and needs improvement. The disincentives inherent in the DRG system increase the risk of quality aspects being sacrificed to price pressure. Patient care can suffer as a result. From the viewpoint of BVMed, the quality of medical care may not be made into an instrument of competition.

Agenda for innovations

A hospital remuneration system is only fit for the future when it can ensure access to advances in medical technology and guarantee an objective and prompt remuneration. Innovative examination and treatment methods are particularly put under pressure in the face of tightened financial stipulations for hospitals. Empirical data confirm that such procedures and technologies are clearly under-represented, measured against the absolute total expenditures of the Statutory Health Insurance (SHI). Thus an annual average of only 50 million euros is provided to pay for innovations. This represents a share of 0.1 percent of the total expenditures of the hospital sector. BVMed has thus published a position paper with the title "Agenda for Innovations in Medical Technology", to convince those involved in the legislation process of the necessity for improving the access to innovations in medical technologies. In this paper, BVMed calls for retaining the supplementary payments, debureaucratizing the innovation clause, providing the hospitals a financing guarantee and not sacrificing quality to competitive interests.



Hernia mesh and plug for hernia care

Health Technology Assessment (HTA)

Study: “Benefit by Innovation”

Costs can be lowered by medical technology innovations which at the same time increase quality and impressively improve the healthcare provided to people in Germany. This is confirmed by the study “Benefit by Innovation” submitted in 2007 by the strategy consultants CEPTON, which was commissioned by BVMed. The benefits of Medtech innovations and their contributions to quality healthcare in Germany were analyzed based on the examples of drug eluting stents, cardiac resynchronization therapy, innovative wound care, adiposity surgery and endoprosthesis. The study sees possible solutions for instance in a transparent process for assessing the cost-benefit ratio of new therapies which includes everyone involved. “A uniform and stringent methodology, the inclusion of all relevant beneficial aspects for the patients as well as a comprehensive cross-sector costing over the entire treatment time period are basic prerequisites for this”, the study states. And further: “Opportunities must be created to introduce innovations into the German healthcare system, also to be able to gather the experience necessary for any assessment at all. The health services research and therapy-specific registers can provide an essential contribution to improving healthcare here. Simultaneously, flexible financing systems must be established which also allow patient-individual co-payments and additional charges.”

HTA for Medical Devices

Professor J.-Matthias Graf von der Schulenburg of Hanover University authored an expert report on the technological evaluation of medical technologies on behalf of BVMed in 2007. The report concludes that a Health Technology Assessment (HTA) is not equally applicable and suitable for every medical device. Therefore, a standardized differentiation according to a decision tree should be carried out to determine whether and when an HTA procedure is suitable and reasonable. The recipients of the technology assessment differ according to the application area of the medical device in question, and could be hospital operators, the Joint Federal Committee, the Institute for Quality and Economic Efficiency in Healthcare (IQWiG), the German Medical Associations, or statutory or private health insurance funds.

Health Services Research

Against the background of the demographic development, medical technology innovations are confronted with the question of medical efficacy as well as cost efficiency of usage in the daily practice of medical care. Especially medical technology innovations are able to render an essential contribution towards making care more economical and expedient. The frequent causal therapeutic approaches help to permanently heal diseases instead of supporting protracted treatments.

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 improved alliances with stronger practice orientation in this still new area. In an event sponsored by BVMed in cooperation with the University of Witten / Herdecke and coordinated by Prof. Edmund A. M. Neugebauer, the relevance of medical care research on medical technology and its application in registers and routine data in medical university research and medical care were examined and explained for the first time.

Technology Assessment by the JFC and IQWiG

Despite the publication of the pronouncement of decisions for the technology assessment by the Joint Federal Committee (JFC), the industry’s opportunities for application, co-determination, and objection have still not been carried out. The reorganization of the JFC and its rules of procedure offers the possibility of further opening up and optimizing the processes involved.

The methodology used by the IQWiG to evaluate gain needs to apply the best available evidence for the technology assessment. Transferability to the clinical routine should also be taken into account.



Products in the technical aids sector:
incontinence catheter



Incontinence treatment
for women



Needles and speech valve for a tracheostomy

Technical Aids

Current Developments in the Technical Aids Sector

The new regulations of the SHI Competition Strengthening Law have been in effect since April 1, 2007. The political objective of the leaders of the coalition is to achieve savings of some 300 million euros in the medical technical aids sector. The current development of expenditures in the medical technical aids sector, however, does not yet show any signs of cost saving. In fact, there has been a slight rise in expenditures. In the first three quarters of 2007 the Statutory Health Insurance spent a total of 3.45 billion euros for technical aids. That corresponds to a mere 3.04 percent of the SHI's total expenditures. In the first nine months of 2006, technical aids' share in expenditures amounted to 2.99 percent. Compared to 2006, the share of technical aids in the total expenditure consequently increased by 0.05 percentage points. The main cause for the moderate rise of the technical aids expenditure is primarily due to the increase of the German value-added tax (VAT). Moreover, although the new law is officially in force, the implementation of its core elements such as brokering of orders by invitations to tender according to the law on allocation by tenders, omission of the accreditation for care providers and the restriction or omission of the patients' right of choice, are still at the beginning of the implementation process.

Legal Ambiguities in the Technical Aids Market

Aside from the question of whether the health insurance funds are public contract parties or not, there are still other areas in which the law allows leeway for interpretation. For instance, there are different interpretations of the law with respect to the application of the transition period for the allocation of a contract by invitations to tender. The reason for this is the specific wording in § 126 of the Social Security Code Book V, whereby the transition period is applied not only for contracts pursuant to § 127 Section 2 and 3 but also pursuant to Section 1 (Specification for Tendering). Accordingly, exclusive invitations to tender may actually only be conducted after December 31, 2008. This legal view is substantiated by a current decision of the Social Court in Frankfurt/Oder of January 4, 2008 (Ref. No.: S 4 KR 285/07 ER) which however is not yet legally binding.

Federal Reference Prices

By latest January 1, 2009 the federal reference prices conclusively lose their status as basis for billing. Instead, they now assume the function of a "benchmark" and form the basis for current and future invitations to tender or contract negotiations. It is assumed that the reference price system will not be further expanded in the future. The annual review of the reference prices with attention to changes in the existing market remains unaffected by this development, however. Thus adjustments have been made in the reference price group system or the reference price amount for technical aids in compression therapy as of January 1, 2008 and for arch supports and visual aids as of March 1, 2008. 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.

Medical technical aids register (HMV)

The National Associations of SHI have promptly adapted the requirements for admitting products to the medical technical aids register. The workability and safety of a product are now considered satisfied by the Declaration of Conformity (CE marking). The new regulations have not yet been implemented with respect to the admission of medical care standards into the medical technical aids register. Currently no one can say when this will happen. In order to systematically implement an increased price and quality competition in the medical technical aids sector, BVMed believes that the healthcare or service aspect must be emphasized more frequently in contracts, invitations to tender and contract negotiations. A prerequisite for this would be to implement the statutory stipulations in the short-term and establish standard nation-wide minimum requirements for medical care. The quality standards developed by BVMed in conjunction with health insurance funds, other associations and patient representatives at the "Quality Network for Technical Aids" (QVH) could serve as the basis. Standards were developed for instance for the ostomy, incontinence and tracheostomy sectors as well as for technical aids against decubitus.



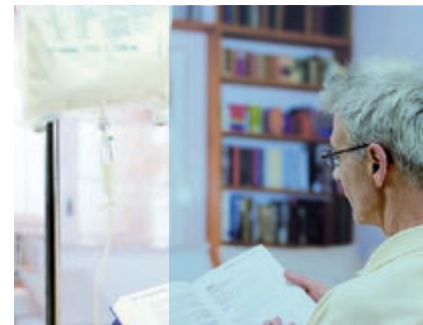
Ostomy bag with integrated base plate



Ostomy care for a young child



Homecare services: modern medical devices improve the quality of life and allow nursing care at home



Homecare

Will invitations to tender slow down the growth market of the future?

Homecare is still considered a most promising growth market. The rising number of persons in need of care is directly countered by the cost squeeze in the statutory health insurance. The provision of technical aids is involved in almost every case of homecare service. With the SHI Competition Strengthening Law, as of April 1, 2007 the invitation to tender has been newly regulated as the first option for concluding a contract for technical aids. In addition, the accreditation of the care provider has been omitted. Altogether, this increases the pressure on the care provider to act.

The health insurance funds in Germany set different standards for implementing the newly created instruments. The individual health insurance funds are not sure when, what and how they should or want to invite tenders. Initial trial runs, however, have brought about a considerable collapse of prices. At the same time the first invitations to tender, e.g. those of the AOK Brandenburg for technical aids in enteral diet therapy, are now pending for decision at the Higher Regional Court. The decision has been deferred until the decision of the European Court of Justice settles the question of whether health insurance funds are public contract parties or not. Once this question is clarified, then it will be conclusive whether the law on allocation by tenders applies and which courts (the Social Court or the Tender Allocation Chamber) is responsible in the event of violations to the competitive bidding procedure for technical aids.

Completed Invitations to Tender

Despite these existing uncertainties on the market and the ongoing legal processes, the health insurance funds have currently employed the invitation to tender instrument in 13 cases. Most of these were conducted in the absorbing incontinence aids sector. At the moment we can assume that the number of invitations to tender will greatly increase in 2008. It is unclear what role the quality of care will play in the supporting tender documents. This aspect can vary enormously depending on the particular product group (PG). Some tender documents show a clear trend towards the lowest price without taking into account the quality of care (AOK Brandenburg – PG 03). Others, in turn, take into account the quality conditions existing on the

market (AOK Mecklenburg/Western Pomerania – PG 29). One thing is clear: the manufacturers and service providers must adapt to the changed prevailing conditions, possibly even with respect to individual health insurance funds.

Electronic Health Card

The introduction of the electronic health card is a topic of some significance to the homecare companies. As homecare can involve 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 have so far been limited to drugs sold only by pharmacists. 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. This year the federal states made the important political decision to establish an electronic Health Profession Register (eGBR). This new institution will take over the task of issuing professional identity cards for the other health professions.

New Models of Care

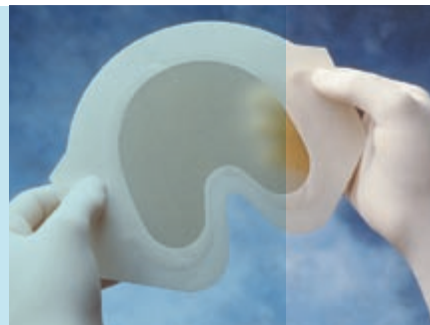
At the end of 2007 there were 5,069 integrated care contracts in Germany with a reimbursement volume of 766 million euros. These figures originate from the German National Institute for Quality Measurement in Health Care (BQS). 103 of the concluded contracts apply on a national level. The SHI Competition Strengthening Law has reinforced the legal basis for new models of care and created further options for action (e.g. gatekeeper or similar models). At the same time, the start-up funding was extended. Some initial implementation proposals have been suggested in individual regions. Examples are the AOK Baden-Württemberg and AOK Hessen. Both health funds have introduced a gatekeeper model which puts the family physician in a central role. This development provides both opportunities and risks for Medtech companies. Conventional distribution channels might possibly have to be newly structured.



Wounds must be attended!
Modern foam dressing



Electrostimulation
in woundcare



Hydrocolloid woundcare dressing

Medical Device Legislation

Amending Directive 2007/47/EC

On October 11, 2007 the directive 2007/47/EC came into effect, amending the European medical device directives regulations 90/385/EEC (active implants), 93/42/EEC (other medical devices, except for in vitro diagnostic medical devices) and directive 98/8/EC (biocides). Whereas the amendment of Directive 98/8/EC applies only to the legal demarcation between in vitro diagnostic medical devices and biocide products, the amendments to the Directives 90/385/EEC and 93/42/EEC contain extensive editorial and content-related alterations to prevailing European medical device legislation.

The most important amendments: Modification and extension of the essential requirements, up-classification of certain products, more rigorous conformity assessment procedures for products of class IIa and IIb, more rigorous requirements on the clinical evaluation labeling requirement for certain medical devices used when plastic softeners (phthalates) were employed and the obligatory statement of known risks for the reuse of single-use products.

The Directive obliges the EU member states to enact and publish the required laws and regulations for national implementation of the amending directive by December 21, 2008. For this purpose the German Medical Devices Act (MPG) must be amended by the end of 2008. The new regulations must be applied nationally by manufacturers with headquarters in the European Economic Area (EEA) as of March 21, 2010.

Regulation of the European Commission on advanced therapy medicinal products

The new EC regulation No. 1394/2007 on advanced therapy medicinal products, including tissue engineering, became effective on December 30, 2007. However, this regulation only applies as of December 30, 2008. The regulation also covers combinations of medical devices and drug products for advanced therapies. But it retains a loophole: products which only contain non-viable tissue and exercise no medicinal effect could henceforth fall under the definition of medical devices by an amendment to the Directive 93/42/EEC.

Third Amendment to the Medical Devices Act (MPG)

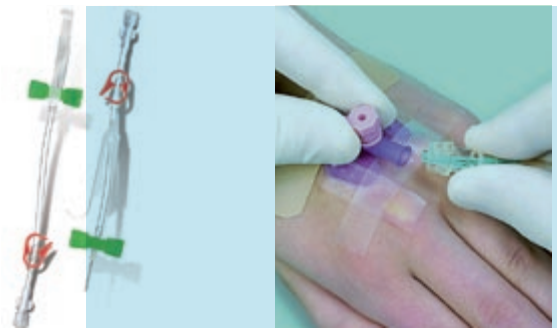
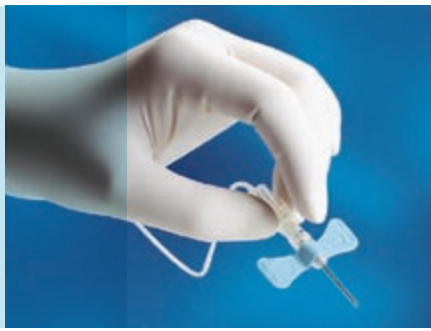
The "Law on amending the Medical Devices Act and other regulations" of June 14, 2007 (3rd MPG amendment) became effective on July 1, 2007. The amendment modified the Medical Devices Act (MPG), the Medicines Act (AMG), the Medical Devices Safety Plan Ordinance (MPSV), the Ordinance of the German Institute of Medical Documentation and Information Ordinance (DIMDI-V) and the German Social Security Code on Statutory Health Insurance Law (Social Security Code Book V). The regulations concerning the in-the-house-manufacturing of medical devices and the reimbursement of pharmaceutical-like medical devices by the statutory health insurance were amended. The exemption regulations on affixing the expiry date, hitherto only applicable to the Federal Armed Forces, now also extend to the government's civil and disaster control.

Ordinance Amending Medical Device Regulations

On February 24, 2007 the "Ordinance amending medical device regulations amendment" of February 16, 2007 became effective. This led to changes of the Medical Devices Ordinance (MPV), the Federal Cost Ordinance – Medical Devices Act (BKostV-MPG), at the same time renamed to: "Federal Fees Ordinance - (BGebV-MPG), as well as to the suspension of the Breast Implant Ordinance (Brust-ImplV) and the MPG-TSE Ordinance. Both ordinances have been integrated into the Medical Devices Ordinance (MPV). Insofar as the new amendment to the Medical Devices Ordinance (MPV) serves the national transposition of the EC Directive 2005/50/EC on the reclassification of certain joint implants, it came into effect on September 1, 2007.

DAMA Establishment Act

The planned adoption of the "Law to establish a German Drugs and Medical Devices Agency" (DAMA-G) failed in the end of 2007. Since the competencies of the Federal Institute for Drugs and Medical Devices (BfArM), which were expanded in the third MPG amendment, continue to apply for medical devices, the failure of this project had no impact on the industry.



Preventing pinprick injuries with safety products

Patient and User Safety / Environmental Issues

Reuse of Medical Devices

Unfortunately, the reprocessing and reuse of single-use medical devices remains the usual practice in Germany. Products which were especially conceived and designed to provide the greatest possible therapeutic success with the least possible negative impact on the patient are frequently filigree constructions whose materials are optimally suited for single use, but by no means for reprocessing and reuse. The manufacturers of single-use products and their trade associations have repeatedly pointed out this fact.

The EU Commission as well as the German Federal Ministry of Health (BMG) commissioned the compilation of empirical reports in 2007, which are to provide information about the conditions and quality of reprocessed medical devices. An initial intermediate result of the BMG survey is already available. The primary deficits are seen with respect to the preservation of the functionality of reprocessed products. BVMed has also called attention to this weak point. In its position statement, BVMed furthermore repeated its call for a ban on reprocessing, and as a “second-best solution” proposed the parity of quality control and product safety demanded of single-use product reprocessors with the manufacturers.

Avoid infections associated with catheters

The proper use of innovative medical devices can make a significant contribution to reducing hospital infections, which occur particularly frequently in connection with the use of central indwelling venous catheters. The efficacy of innovative medical devices to reduce infections has been substantiated by a multitude of studies. Nonetheless, pinpointing a unique causality is made difficult considering the multi-factor causes of hospital infections. Even in the case of an overwhelmingly clear data situation, it takes much too long before the pertinent guidelines of the Robert Koch Institute (RKI) have been adapted to the new findings. A new BVMed sub-group is therefore seeking closer cooperation with hospital hygiene experts. Ideally, a permanent forum of experts will grow out of this initiative which would ultimately provide suppliers of innovative medical devices the possibility of neutrally and promptly evaluating and communicating the contribution their products could make towards the prevention of infection.

User safety through safe instruments

Sharps injuries with potential infectious instruments are a part of medical routine. In the worst case, injuries caused by pointed or sharp instruments may result in contracting hepatitis B or C infections and HIV. With the revision of the “Technical Rules for Biological Work Materials” (TRBA 250), it is mandatory to use safe working devices in medical care for specific patient groups as well as in emergency care, emergency rooms and in prison hospitals. The transition period expired on July 31, 2007. For this reason, BVMed organized a workshop for representatives of medical facilities, the relevant accident insurance companies and the authorities to demonstrate the most suitable ways of implementing the technical guideline TRBA 250.

Environmental Issues: REACH, WEEE / RoHS, German Packaging Ordinance

As of July 1, 2008 the initial obligations come into effect prescribed by REACH (European Regulation on the Registration, Evaluation, Authorization and Restriction of Chemicals). In a joint workshop with the German Diagnostic Manufactures Association (VDGH) held on April 19, 2007, BVMed gave its members the opportunity of receiving expert information on the REACH obligations and sounding out the possible consequences for the medical technology sector.

Such consequences for the industry might be contained in the pending revisions of the European guidelines for avoiding pollutants in electrical and electronic devices, RoHS (Reduction of Hazardous Substances), and how to dispose of these devices, WEEE (Waste Electrical and Electronics Equipment). We can thus expect that the hitherto prevailing exception from the RoHS for medical devices will no longer apply at least to some extent. Such devices would then also be subject to the ban on pollutants. The original proposal for the 5th amendment to the German Packaging Ordinance stipulated that hospitals could no longer take advantage of dual disposal services such as the German Dual System (DSD AG). In its position statement, BVMed explained the possible consequences for manufacturers and hospitals and discussed the implementation options with a number of disposal services.



BVMed media seminar in Berlin



Media dialog to present the Medtech compass

Communications / Press

The developments in the Medtech industry in Germany are keenly followed by the public. Physicians and health insurance funds as well as patients want to be informed about new methods of treatment. Policymakers and the media are increasingly interested in Medtech as an important sunrise industry. For medical technology companies, this means that on the whole their communication efforts must be professionalized. BVMed offers its support to all stakeholders by holding its annual Medtech Communications Congress. In 2008 it will be held for the fourth time, and for the first time in cooperation with SPECTARIS, on May 26 and 27 in Frankfurt.

TV Service Medical Technology

The objective of BVMed's "TV Service Medical Technology" at www.tvservice.bvmed.de is to better inform patients and users about new medical technology procedures and to improve the positioning of new medical technologies on television. BVMed's TV service provides professional footage including interviews which may be used by TV broadcasting companies free of charge. In addition, ready-made patient films can also be downloaded from the internet or ordered on DVD free of charge. Furthermore, there are radio spots about various medical technologies. In the meantime 15 film projects have been completed, most recently on telecardiology and artificial intervertebral disk replacements. Broadcasts have appeared on 30 different TV news shows viewed by over ten million people. Added to this are some 1,500 DVD orders by information disseminators.

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 about 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 2007, Aktion Meditech reached over 75 million readers via 160 articles in popular press magazines. Further activities consisted of an annual patient group symposium, media seminars, four so-called "Berlin Talks" for policymakers and representatives of hospitals and sickness funds, as well as a quarterly newsletter. More at www.aktion-meditech.de.

Media Work and Image Cultivation

While Aktion Meditech continues to attract a lot of popular press attention, BVMed's media work concentrates on medical journals, daily newspapers and economic publications. 2007's media tools were, among others, almost 100 press releases, numerous press conferences and background talks (BVMed Media Dialog), articles and essays as well as media cooperations. 40 million reader contacts were achieved with more than 600 articles. The continuous supply of information is supplemented by weekly newsletters to 6,100 subscribers and an e-mail service presenting up-to-date news as well as by press releases and monthly BVMed reports in English. In early 2008, BVMed furthermore launched an information campaign for an effective and transparent cooperation between industry, physicians and medical facilities entitled "Medtech Compass" www.Medtech-kompass.de. 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 2007 or the seventh BVMed press seminar in November 2007.

Internet and Extranet

BVMed's website at www.bvmed.de registered over 1.5 million individual visitors and 23 million hits in 2007. That is almost 60 percent more than in the previous year (898,000 individual visitors). The average length of each visit on the over 6,000 individual internet pages of the BVMed website amounted to slightly over four minutes. Every visitor opened an average of twelve different sub-pages. In early 2008, the website's visual appearance was modernized and multimedia contents incorporated on every page via Flash Media. BVMed's extranet offers a central information and communication platform for all member companies.

10th E-Health Conference

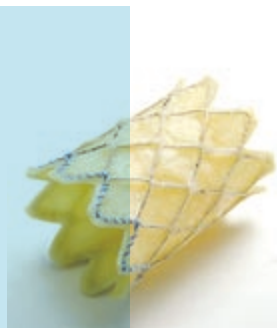
With its so far 10th E-Health conference in February 2008, BVMed established an "E-Procurement get-together" and an information and communication platform for hospitals, manufacturers and service providers. The jubilee conference on e-health topics directs the focus beyond the electronic procurement processes to the entire spectrum of e-health projects relevant to the Medtech industry.



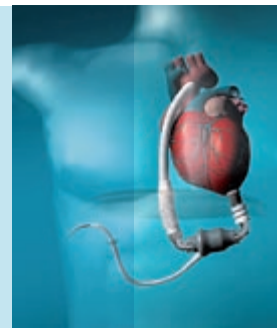
Medical technologies in cardiology: Pacemaker for cardiac resynchronization therapy (CRT)



Electrode for cardiostimulation



Cardiac valve replacement (pulmonary valve)



Implantable cardiac support system



Use of a cardiac pacemaker system in surgery

Reports from BVMed's Expert Committees

Focus Groups

Focus Group "Legal Issues" (AKR)

AKR holds joint meetings with the members of the "Network Medical Devices Law", a group of eleven specialized lawyers. The focus group 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 204 court rulings on medical devices. In May 2008, the group conducted the third annual BVMed symposium on "Current legal issues pertaining to medical devices".

Focus Group

"Regulatory and Public Affairs" (AKRP)

Among the key issues addressed by AKRP in 2007 were the requirements on labeling, certification and clinical evaluation of medical devices, the relation of the Medical Devices Act to radiation protection law and x-ray law, official market surveillance and regulations for medical devices in non-EU countries. AKRP is actively involved in revising BVMed publications on medical device legislation and working intensively on standardization issues. In 2008, the focus group will host two information sessions on the practical implementation of the EC Directive 2007/47/EC and the Medical Devices Act (MPG).

Focus Group "Environment" (AKU)

The AKU sub-group REACH initiated the compilation of a list of "REACH-relevant medical devices" and substantiated the pending obligations and consequences of the new EU Chemicals Policy for the Medtech industry. The AKU sub-group "Electronic Devices Act" focuses on practical experience in implementing the law in connection with the Stiftung Elektro-Altgeräte Register (EAR) foundation. The EAR regulation for the device type "medical devices" was reconciled and passed there. The AKU sub-group "Packaging Ordinance" is occupied with the fifth amended version of the ordinance and critically examines the various disposal solutions and concepts with disposal service providers.

Sectoral Interest Groups

Sectoral Interest Group "Eye Surgery" (FBA)

The FBA sectoral interest group consists of cooperating manufacturers of ophthalmological medical devices. The group was renamed from "Intraocular Lenses" to "Eye Surgery" to reflect the broader product range of its members. The "Reimbursement" sub-group wrote a White Paper describing two models which could ensure the long-term certainty of reimbursement for patients with high-quality intraocular lenses. The FBA "PR Concept" sub-group supports an initiative which aims to inform a broader public about the particular characteristics of innovative intraocular lenses and their benefits to the patient.

Sectoral Interest Group "Blood" (FB Blood)

The members of this group are manufacturers of blood bags and devices for apheresis. The sectoral interest group is primarily concerned with the regulatory requirements on these particular products at the interface of medical devices and pharmaceutical law.

Sectoral Interest Group "Brachytherapy" (FBBT)

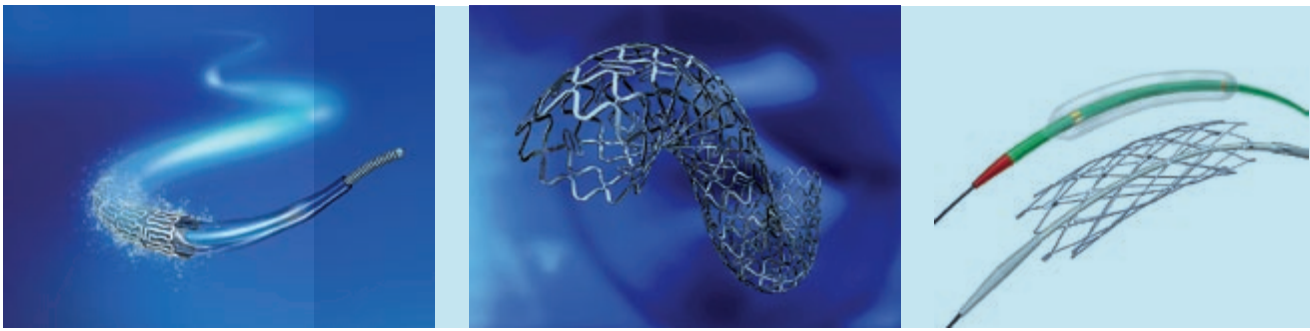
FBBT's working group "Interstitial Brachytherapy" (PG IBT, seed method for prostate cancer) promotes the admission of this form of therapy into the reimbursement catalog for office-based outpatient care. The application to admit the outpatient reimbursement catalog is currently pending at the JFC. The IQWiG provided active support of the evaluation of gain of this method with position statements and hearing. Moreover, quality standards will be developed with the users.

Sectoral Interest Group Diagnosis Related Groups – Hospital Financing (FB DRG)

The FB DRG accompanies the regulatory elaboration of hospital financing under special consideration of the appropriate representation of medical devices. It responded to the Federal Ministry of Health's questionnaire and provided support to the position statement at the state hearing. The sectoral interest group coordinates proposals for further development from the DRG and OPS in the BVMed. In addition, the group develops BVMed continued education schemes for this sector.

Focus Groups

- Legal Issues (AKR)
- Regulatory and Public Affairs (AKRP)
- Environment (AKU)



Medical technologies for the vessels: different coronary stent systems for vascular blockage

Sectoral Interest Group

Eye Surgery (FBA)

Blood (FB Blood)

Brachytherapy (FBBT)

Diagnosis Related Groups – Hospital Financing (FB DRG)

First-Aid Materials (FBEH)

Ethylene Oxide Sterilization (FBEO)

Trade / Homecare (FBHH)

Health Technology Assessment (FBHTA)

Homecare (FBHC)

Infusion Therapy (FBIV)

Cardiac Medical Devices (FBKMP)

Artificial Feeding (FBKE)

Health Insurance Law for Care Providers (FBLL)

Medical Technology Implants (FBMTI)

...

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

The FBEH is primarily concerned with the adaptation of first-aid materials to the current state of modern emergency and disaster medicine, and their harmonization with the pertinent standards. The sub-group “Communication” (AGK) of these manufacturers of first-aid kits for cars relies on continuous press relations work to inform the public of the diverse deployment potential of first aid kits.

Sectoral Interest Group “Ethylene Oxide Sterilization” (FBEO)

The FBEO analyzed the consequences of the Biocides Directive on the ethylene oxide sterilization of medical devices. The members are working to ensure that the requirements of the directive do not lead to a ban on the sterilization of medical devices with ethylene oxide. A short-notice renunciation of this sterilization method would spell death for a large number of vital medical devices and is therefore unjustifiable.

Sectoral Interest Group “Trade / Homecare” (FBHH)

In order to better accommodate the particular interests of the trade companies represented by BVMed, a separate platform was established for forming political opinion and exchanging ideas among the affected trade companies. 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 in coordination with the other affected sectoral interest groups.

Sectoral Interest Group “Health Technology Assessment” (FBHTA)

The FBHTA accompanies the technology assessment processes for medical devices. It develops methodical approaches to the HTA of medical technologies. It accompanied the studies “Application of HTA for Medical Devices” and “Benefit by Innovation”. Furthermore the sectoral interest group accompanies the HTA program of the German Institute of Medical Documentation and Information (DIMDI) and the still new application area of healthcare research. The FBHTA compiled position statements on the

evaluation of gain methodology by the IQWiG and the Joint Federal Committee (JFC). A special seminar provided information about the practice-relevant application of HTAs and their significance for the manufacturers.

Sectoral Interest Group “Homecare” (FBHC)

The FBHC communicates the concept of homecare and the underlying therapies and quality aspects to third parties. The sector is characterized by a good deal of political upheaval. After the SHI Competition Strengthening Law follows the reform of the long-term care insurance, to which the FBHC has worked out a position statement. Discussions were conducted with the relevant members of parties sitting in Parliament. Different industry-relevant meetings (e.g. the Trade Fair and Congress for Hospital and Home Care in Leipzig) were used to discuss the benefit and quality of homecare with all policy makers. In order to speed up interdisciplinary networking, the general agreement was devised with the German Association for Medical Rehabilitation (DEGEMED).

Sectoral Interest Group “Infusion Therapy” (FBIV)

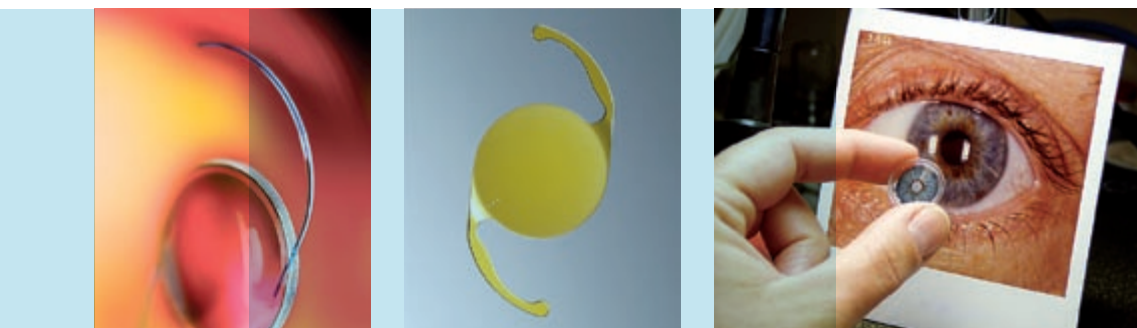
This sectoral interest group prepared a proposal for the restructuring of product group 03 of the medical technical aids register based on the particular areas of care (parenteral feeding, chemotherapy, pain therapy, etc.). The proposal was presented to the federal association of guild health insurance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

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 cardiopulmonary bypass machines. Examples of this are the telecardiological applications for active implants and the less invasive insertion of cardiac valves by means of catheter technologies.

Sectoral Interest Group “Artificial Feeding” (FBKE)

The discussion on the revision of the pharmaceutical guideline on the reimbursement of oral supplement and



To see again – medical devices in eye surgery: modern intraocular lenses (IOL), artificial iris, production of artificial lenses

tube feeding represented the main focus of this sectoral interest group. In the meantime, the judicial opinions of the Cologne Social Court are available. The Federal Ministry of Health has lodged an appeal, so that the case will appear before the Higher Social Court of Essen in the second instance. A commentary was written about this. In order to promote an even more effective exchange within the industry, a sub-group was established with the Dietetic Association. Another main agenda item was the Europe-wide invitation to tender of the AOK Brandenburg on technical aids for enteral diet therapy of April 2, 2007. The AOK did not award the tender to any of the bidders, since the judicial review of the invitation to tender is still pending at the Higher Regional Court of Brandenburg.

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 scope of interrelation among sickness funds, care providers and patients. The group is particularly concerned with the first nation-wide invitations to tender of the two health insurance funds Kaufmännische Krankenkasse (KKH) and BARMER-Ersatzkasse. In 2007, the FBLL also initiated an event for the intensive exchange of views with the health insurance funds on legal questions concerning healthcare benefits. This dialog will be continued in 2008.

Sectoral Interest Group “Medical Technology Implants” (FBMTI)

FBMTI represents the manufacturers of artificial joints. Healthcare compliance was an important topic of this sectoral interest group last year. The group thoroughly examined which forms of desired cooperation are permissible between the economy and science, hospitals and medical technology companies. Also considered were the kinds of behavior acceptable on the part of medical devices consultants. The FBMTI discussed the introduction of an endoprosthesis register. There is a general consensus for this idea within the group. However, before establishing such a register the questions of data sovereignty and financing must be clarified.

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

The FBMW advocates the prescribability and reimbursability of hydroactive / modern wound care products. Aside from the already known educational media and the annual information event, now special training sessions will also be conducted for medical specialists in cooperation with their professional association. Altogether over 1,000 physician’s assistants have already been trained this way.

Sectoral Interest Group “Sharps Injury Prevention” (FBNSP)

This group consists of manufacturers of medical devices with safety mechanisms to protect against cut, stab, and scratch injuries in daily medical routine. In January 2007 this sectoral interest group conducted its 3rd workshop with representatives from occupational safety, accident insurance and daily routine medical care and analyzed the possibilities of further optimizing the protection against sharp injuries. The FBNSP elucidated the new requirements of the Technical Guideline for Biological Working Materials.

Sectoral Interest Group “Renal Replacement Therapy” (FBNE)

In 2007 the suppliers of dialysis technology products established the “Kidney Alliance”. The initiative aims at explaining the significance of these life-sustaining medical technologies and the prevailing conditions of such services, and offers cooperation with like-minded organizations. In a Round Table Discussion held in September 2007, the goals of the alliance were presented for the first time to representatives of physicians and patients, nurses and dialysis centers. Other public relations activities will follow.

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. In cooperation with the medical expert societies and professional associations, advanced and ongoing training concepts and events are provided product-related support.

- ...
- Modern Wound Care Products (FBMW)
- Sharps Injury Prevention (FBNSP)
- Renal Replacement Therapy (FBNE)
- Peripheral Vascular Medicine (FBPG)
- Absorbing Incontinence Care (Manufacturers) (FBI-H)
- Practice Supplies, Prescribable Supplies, Medical Dressings (FBSRV)
- Supply of Sterile Goods (FBSV)
- Ostomy / Incontinence Care (FBSI)
- Radiation Sterilization (FBS)
- Therapeutic Apheresis (FBTA)
- Tracheostomy / Laryngectomy (FBTL)
- Spine Surgery (FBSC)



Medical technology moves: implants for bones and joints – Hip implant, Knee implant, Shoulder prosthesis, Ankle joint prosthesis

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

The FBI-H is particularly concerned with the necessary contents for invitations to tender, e.g. the inclusion of relevant quality standards, as well as the importance of having separate invitations to tender between the outpatient and inpatient sector. The FBI-H contributed to the creation of quality standards for absorbing incontinence care products.

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

The impact of the new uniform valuation standard (EBM) on the reimbursement and prescription of medical material supplies in the SHI physician sector are the focus of FBSRV activities. Contacts to the National Association of Statutory Health Insurance Physicians and state apothecary associations were built up or strengthened. One result of the cooperation with the national SHI association is the new information service for the office-based physician sector, the newsletter “Medtech ambulant” (Medtech Outpatient).

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 safe use. If required, specific issues are followed up in FBSV’s sub-groups or in the sectoral interest groups “Ethylene Oxide Sterilization” and “Radiation Sterilization”.

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

The FBSI advocates the preservation and long-term assurance of healthcare quality for ostomy and incontinent patients. It developed respective medical care standards together with patient representatives and the health insurance funds. Moreover the FBSI has supported the National Associations of SHI with current market data for the annual review of the nation-wide reference prices for draining incontinence aids and ostomy products.

Sectoral Interest Group “Radiation Sterilization” (FBS)

The FBS is the forum of operators of radiation facilities for sterilizing medical devices. The main themes of the FBS are the implementation of regulatory requirements, for instance by the relevant laws and regulations, and disseminating explanatory information about the importance of radiation sterilization.

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, thus rendering a customary statistical assessment inapplicable.

Sectoral Interest Group “Tracheostomy / Laryngectomy” (FBTL)

The FBTL contributed to the creation of necessary medical care standards in this sector. Other important topics are the implementation of the SHI Competition Strengthening Law by the health insurance funds, current billing problems and the changes in the medical technical aids register.

Sectoral Interest Group “Spine Surgery” (FBSC)

The FBSC worked on further developing the coding guideline for the DRG system in cooperation with the relevant medical expert societies. It also actively promoted the further training of the younger medical professional generation in the application of these technologies.

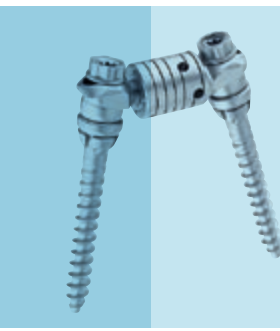
Working Groups and Sub-Groups

Working Group “Decubitus Forum” (DF)

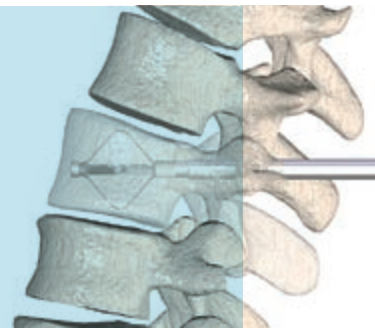
The forum participated in the compilation of quality standards for the long-term assurance of existing healthcare quality with anti-decubitus products. Furthermore it developed a guideline for reprocessing anti-decubitus products.



Artificial intervertebral disk replacement



Spinal implant



Treatment of a vertebral body fracture

Working Group “Electronic Health Card” (PG eGeK)

The working group “Electronic Health Card” is concerned with all matters pertaining to the electronic health card and the 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. The working group maintains close contact to the Federal and State Working Group concerned with this topic. It also actively supports the process of introducing an electronic Health Profession Register, which might possibly take over the task of issuing professional identification cards.

Working Group “PVC” (PG PVC)

The most important theme of the PG PVC centers around knowledge and measures involving all aspects of the softening agent DEHP. The preliminary report of the European Union of June 2007 on the safety of medical devices made of DEHP-PVC refers to the scant evidence of possible damages and explains that a risk evaluation of alternative softening agents was previously not possible. On the other hand the amendment of the Medical Device Directive of October 2007 already demands that certain medical devices with DEHP-PVC must be accordingly labeled in the future. It’s still not absolutely clear how the labeling has to be done.

Working Group “Reuse” (PG Reuse)

The “Reuse” working group is concerned with the reprocessing and reuse of medical devices. Its main topic remains the reuse of single-use products, which takes place in defiance of the manufacturer’s specifications. The PG Reuse developed an extensive position statement on the survey initiated by the Ministry of Health in preparation for its empirical report on the reprocessing of medical devices. The annual MedInform event on the topic showed that there continues to be deficits in the reprocessing of single-use and re-usable products.

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

PG SAO coordinates proposals for the inclusion and financing of medical technologies in the service catalog for outpatient surgery and the reimbursement catalog for

office-based outpatient care. An intensive dialog is being conducted with representatives of the contract partners and users about the proper development and representation of technologies.

Working Group “Tissues” (PGT)

The PGT communications deal with the range of medical products manufactured with animal or human tissue, cells or blood, vital or non-vital. These products do not always fall under medical device legislation. The European Regulation on Advanced Therapy Medicinal Products, which became effective on December 30, 2007, regulates products made of cells and tissue used as pharmaceuticals. However, loopholes and questions of delimitation remain.

Sub-Group “E-Standards” (AGE)

A new sub-group “E-Standards” was formed in June 2007. It consists primarily of members of the former sub-group “Barcodes” and is concerned with communication and information standards in public healthcare, such as for example auto-identification systems (bar codes, RFID) or classification systems for medical devices. In discussion with the suppliers of the leading medical device classification systems eCI@ss and GPI, the group attained a cooperation commitment from both companies. At a meeting with representatives of major hospital buying cooperatives, the participants recommended using the eCI@ss standard to classify medical devices in the future.

Sub-Group “Catheter-related infections” (AG Katheter)

In September 2007 the sub-group “Catheter-related infections” was formed. The members consist of suppliers of catheters, surgery materials, filters and disinfectants, and want to emphasize the contribution of innovative medical devices to the reduction of infections and help promote a rapid and large-scale implementation of new findings about infection prophylaxis. Possibilities of joint activities should now be decided upon in a round of talks to be held with hygienists.

Working Groups and Sub-Groups

- Decubitus Forum (DF)
- Working Group Electronic Health Card (PG eGeK)
- Working Group PVC (PG PVC)
- Working Group Reuse (PG Reuse)
- Working Group Material Costs and Outpatient Surgery (PG SAO)
- Working Group Tissues (PGT)
- Sub-group E-Standards (AGE)
- Sub-group Catheter-related infections (AG Katheter)
- Working Group Legal Issues (AG Legal Issues)



BVMed's Head Office in Berlin



In dialog with policy makers and the media: BVMed chairman of the board Dr. Meinrad Lugan with Dr. Klaus-Theo Schröder, State Secretary at the Federal Ministry of Health, and the TV journalist and media consultant Alexander Niemetz

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Director General BVMed

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Director General

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BVMed Health Discussion Group with Dr. Faust, member of the Bundestag



Passing the torch at BVMed: Dr. Meinrad Lugan (center) takes over the office of chairman of the board from Anton J. Schmidt (right). Left in the photo: BVMed Director General and member of the board Joachim M. Schmitt



from left to right: BVMed Director General Schmitt with DAK boss Rebscher and Prof. von der Schulenburg at the BVMed Innovation Forum



A fixed institution: BVMed summer festival in Berlin

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. Home-care 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
- :: 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

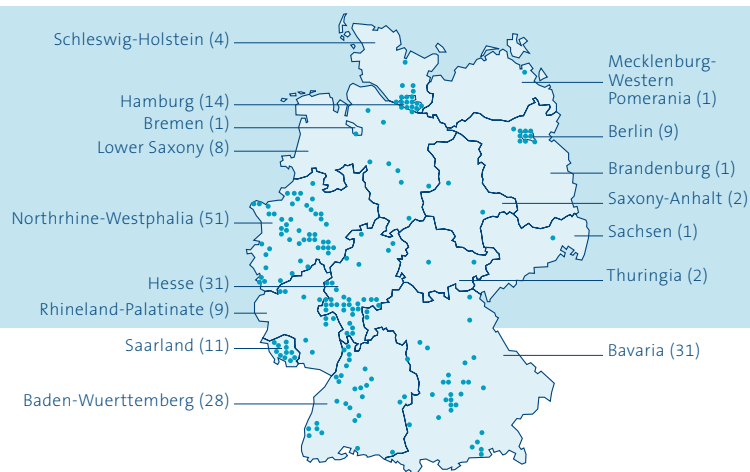
4. Representation

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 April 2008: 204 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 GmbH
*Abiomed Europe GmbH
ACRITEC Gesellschaft für ophthalmologische
Produkte mbH
Advanced Medical Technologies AG
*AESCLAP AG & CO. KG
AGA Medical Deutschland GmbH
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
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Andreas Fahl Medizintechnik-Vertrieb GmbH
*Ansell GmbH
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ArthroCare Deutschland AG
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
Berlin Heart GmbH
BGS Beta-Gamma-Service GmbH & Co. KG
Biomet Deutschland GmbH
*BIOTRONIK GmbH & Co.
*Boston Scientific Medizintechnik GmbH
Bristol-Myers Squibb GmbH & Co. KGaA
BSN medical GmbH

C

C.R. Bard GmbH
Cardinal Health Germany 206 GmbH
CeramTec AG Geschäftsbereich
Medizintechnik
Chemische Fabrik Kreussler + Co. GmbH
Clinical House GmbH
*Coloplast GmbH
Coltène /Whaledent GmbH + Co. KG
COOK Deutschland GmbH
CORDIS Medizinische Apparate GmbH
Corin Germany GmbH
*Covidien Deutschland 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 Germany GmbH
EMKA Verbandstoffe GmbH & Co. KG
ev3 GmbH

F

FOR LIFE Produktions- und Vertriebs-
gesellschaft für Heil- und Hilfsmittel mbH
Franz Kalff GmbH

*FRESENIUS SE
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
GHD Gesundheits GmbH Deutschland
Given Imaging 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
*HumanOptics Deutschland GmbH & Co. KG

I

IMI Intelligent Medical Implants GmbH
Impulse Dynamics GmbH
INVATECH Gesellschaft für fortschrittliche
Medizintechnik mbH & Co. KG
Isotron Deutschland GmbH

J

*Johnson & Johnson MEDICAL GmbH

K

Kaneka Pharma Europe N.V. German Branch
Karl Beese (GmbH & Co.)
KARL OTTO BRAUN GmbH & Co. KG
KCI Medizinprodukte GmbH
KEIMED GmbH (HSC)
Kettenbach GmbH & Co. KG
KRAUTH medical KG (GmbH & Co.)
KREWI Medical Produkte GmbH
Kyphon Deutschland GmbH

L

Leina-Werke GmbH Verbandstoffe Medical
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LogoMed GmbH
Lohmann & Rauscher
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Ludwig Bertram GmbH

M

MacoPharma International GmbH
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Maimed Medical GmbH & Co. KG
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Technical aids for a better quality of life:
bandages, orthotic devices, prostheses and compression hosiery

Modern leg prosthetic

Thought-controlled
arm prosthetic

medac GmbH –
Gesellschaft für klinische Spezialpräparate
*medi GmbH & Co KG

Medi-Globe GmbH
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MEDOS Medizintechnik AG
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Mr. Clean – Gesund Schlafen GmbH
Mundipharma GmbH
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N
NAWA Heilmittel GmbH
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noma med GbR
Novo Klinik-Service GmbH

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Oncura GmbH
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ORMED GmbH
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*Peter Brehm GmbH Chirurgie-Mechanik
pfm Produkte für die Medizin
Aktiengesellschaft

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Pharm-Allergan GmbH
(mit Inamed Aesthetics GmbH)
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Plus Orthopedics AG
PMT Präzision-Medizin-Technik GmbH,
Weiskirchen
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
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Fabrik GmbH
Sangro Medical Services GmbH
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Sanitätshaus Aktuell GmbH
SCA Hygiene Products GmbH
*SENNEWALD Klinikprodukte GmbH
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Servox GmbH
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*Stryker GmbH & Co. KG
*SYNTHES GmbH
System France
SÖHNGEN – W. Söhngen GmbH

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Tutogen Medical GmbH

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VYGON GmbH & Co. KG

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WERO-medical Werner Michallik
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Z
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