BVMed
Enhancing Health

Annual Report
2008/2009

The Medical
Technology Companies
www.bvmed.de

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

Contents

IMPRINT

Publisher BVMed – German Medical Technology Association
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Berlin, March 2009

Dr. Meinrad Lugan
Chairman of the Board of BVMed

Introduction

Process optimization and drive for quality can succeed through cooperation

Our common aim is to keep our healthcare affordable at a high level of quality for everyone. To do so, we need continual process optimization and a stronger quality consciousness in healthcare. This requires the joint efforts of health insurance funds, physicians, hospitals and medtech companies.

We need competition to get the best possible medical technology care, and we must counteract the trend towards cheap medicine with joint projects for the benefit of patients.

The introduction of the health pool is indeed cause for great insecurity in 2009. But it also offers the opportunity for health insurance funds to redirect their attention towards the quality of service to patients. The first year of the health pool offers the chance of promoting new alliances for optimized processes, improved quality and medical advances in the healthcare market. To this end we need more cooperation among health insurance funds, hospitals, physicians and medtech companies in order to provide people with high-quality care using modern medical technologies.

Criteria for a genuine quality competition must be developed and definitively prescribed. One positive example of this is the set of quality standards in the supply of technical aids developed by care providers together with the national associations of the Statutory Health Insurance and their medical review board. Other positive examples include guidelines of the medical expert societies as well as projects such as the endoprosthesis register, which will provide new insights in the outcome research sector. The work of the new institute for cross-sector quality assurance must take these developments into account.

The long-term goal has to be the distribution of funds according to the needs of patients and effective quality parameters, and not according to the different healthcare sectors. We require control instruments suited for making quality measurable and appropriately recompensing good quality. And we need joint projects for process optimization. This also makes good economic sense, since high-quality healthcare helps to avoid subsequent costs.

Yours sincerely,

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 (March 2009), some 216 industry and trade companies are represented by BVMed. This amounts to eleven more companies than last year. A total of 24 companies became BVMed members in 2008. These gains were offset by 14 resignations or mergers. A complete list of members is provided on pages 22 / 23.

Market Development

The mood in the industry has distinctly deteriorated compared to last year. The BVMed companies registered an average sales growth of 5.4 percent in 2008, which is primarily based on quantity increases. Last year the increase in turnover measured 7 percent. The still fairly positive sales trend, however, is offset by the persistent downward pressure on prices and greatly increased raw material and energy prices. The profit situation in the medtech sector is therefore distinctly strained. The extremely broad spread among various product areas must also be taken into consideration. While staple products show continued 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 72 member companies participated, yielded the following most significant results:

> Despite the strained economic situation, the medtech industry remains a job engine. As in the previous year, 55 percent of the surveyed companies created new jobs. In 27 percent of companies, the number of employees remained stable. Projected on the total number of BVMed member companies, the members have created a total of about 4,200 new jobs compared to last year.

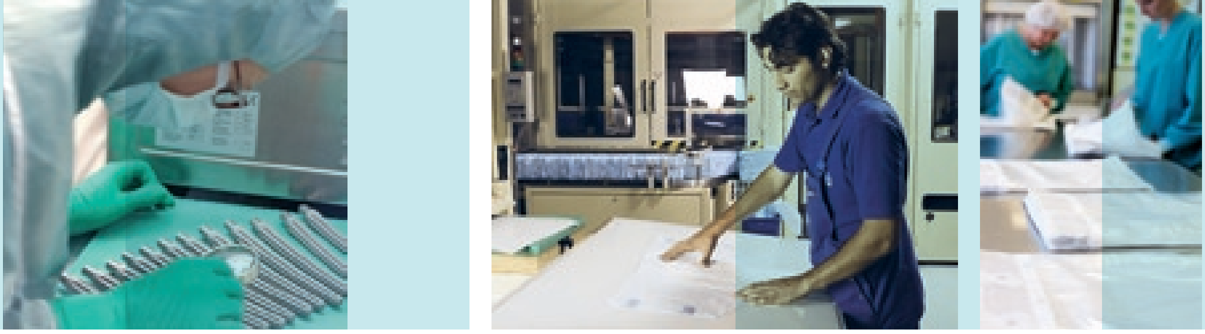
> On an average, the companies invested approximately 7.2 percent of their sales turnover in research and development. The value lies at an excellent 9 percent if one subtracts the pure sales organizations and thus considers only the researching medtech companies separately.

> The sector's innovative capability is reflected in the fact that about 84 percent of the companies plan to launch new products and methods on the market in 2009. As expected, most innovations affect the hospital sector.

> When asked whether Germany provides a good environment for the medtech industry, BVMed companies expressed strong approval and appreciation. The main factors cited are primarily the high level of medical care of patients (67 percent), large number of well-trained physicians (56 percent) as well as high standards in clinical research (50 percent). 27 percent cited the rapid marketing authorization as strength. The primary criticism centers on the low level of reimbursement in Germany compared to other European countries.

> As in the previous year, 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). The increased raw material and energy costs have advanced to second place on the list of obstacles this year. 49 percent of responding companies cited this factor.

> Above all, the BVMed companies want public health policy to provide more flexibility in the reimbursement systems. 57 percent advocate more own responsibility of patients, for example by models with additional or variable charges to the fixed refund guarantee in certain areas of medical technology. 43 percent want more freedom of choice for the insurant. Then comes the proposal for suspending budgeting in the hospital sector (44 percent) and an outcome-oriented remuneration of healthcare services (40 percent). 33 percent advocated the model „basic care plus supplementary insurance".



(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 2008 / 09

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 4.4 million people are employed in healthcare. Thus, about every tenth job in Germany is based in the health economy. 245 billion euros in total are spent on health. This represents a share of 10.6 percent of the gross domestic product, thus making healthcare an even more significant sector than, for instance, the automotive industry (9.7 percent of GDP).

Expenditure for Medical Devices in Germany

In Germany healthcare spending in the medical devices sector (without capital goods) amounted to more than 22 billion euros. Of this amount, about 10.9 billion euros account for medical-technical aids, 9.7 billion euros for other medical supplies and about 1 billion euros for the sector of medical dressings, which is listed in the category “pharmaceuticals”. The share of Statutory Health Insurance in the total expenditure incurred amounted to over 14 billion euros.

Jobs

The medical technology industry employs 95,000 people in nearly 1,250 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 170,000 people in Germany in more than 11,000 companies. Another 29,000 people are employed in the retail trade for medical and orthopedic products. Approximately 15 percent of the employees work in Research and Development (R & D), with a trend toward 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 6.9 percent to 17.3 billion euros in 2007. The domestic sales volume rose by 7.3 percent to 6.2 billion euros, the export sales by 6.7 percent to 11.1 billion euros. About 41 percent of exports went to countries of the European Union, 22 percent to North America and 14 percent to Asia in 2007. In export, Germany ranked second worldwide, with a world trade share of 14.6 percent, behind the USA (30.9 percent) but distinctly ahead of Japan (5.5 percent).

Worldwide Growth Market of Medical Technologies

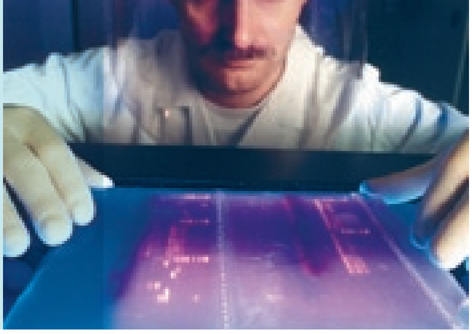
The medical technology industry is a worldwide growth market. Advances in medical technology, demographic development with more and more older people and the expanded idea of health will ensure that this remains so. The demand for healthcare services will continue to rise. Patients are increasingly prepared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

The world market for medical technologies amounts to about 220 billion euros. After the USA at 90 billion euros, the European market at 65 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 22 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 IT (6.7 percent).


Production of pacemakers

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

From the idea to application: Three steps to medical-technical progress

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's policy concerns can be portrayed on the basis of three stages towards medical progress:

FIRST STEP

Ideas for medical-technical progress

Physicians are often the source of ideas for innovations or advanced developments. The prevailing conditions for new ideas are outstanding in Germany. We have well-trained doctors, researchers and engineers and a high standard of clinical research. These are the best prerequisites for developing new products and processes.

SECOND STEP

From the idea to the finished product

The idea for a product or process is taken up and developed by physicians, technicians, and engineers in the companies. The development of the technology itself is geared to maximum safety requirements. The process is accompanied by a risk analysis and assessment prescribed by law which compares the possible potential dangers of the respective method to its possible benefits. Owing to the detailed risk assessment, the CE marking stands for comprehensive safety. Furthermore – and this applies only for medical devices – it also stands for performance capability. Because the law prescribes that a clinical trial is conducted for every medical device. This regulatory framework for medical devices with graduated risk requirements has proven reliable and should be retained.

THIRD STEP

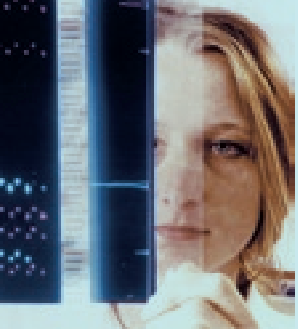
The new product in application

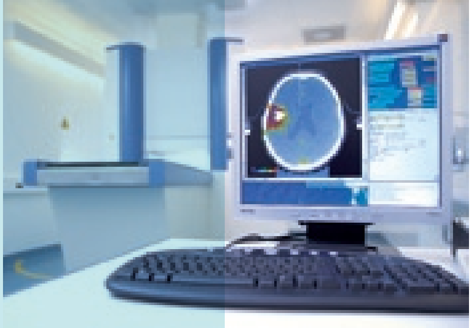
The market authorization, however, does not yet ensure that the new product or process will also be reimbursed by the health insurance funds. But due to the dynamism and speed of innovation in the medtech sector, it is important that new products and processes can be rapidly introduced. From the viewpoint of BVMed, among other things the following points are important:

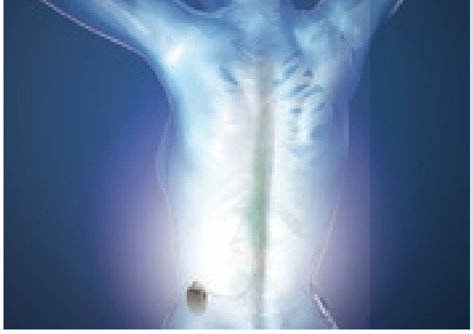
- We advocate retaining the principle of "permission with the reservation of prohibition" in the hospital sector. This principle is important for the innovative abilities of hospitals and the medtech sector. Many innovations are initially applied in hospitals. Medical technological innovations in hospitals are subject to reimbursement by Statutory Health Insurance, unless there has been a negative decision of the Joint Federal Committee (JFC). 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.
- Medtech companies need unambiguous, but also objective directives on the evaluating criteria in the technological assessment procedures (HTA). Then it will also be possible to conclude the procedure of the JFC more rapidly.
- We advocate greater flexibilization of the reimbursement schemes. We support stronger own responsibility of the insured. We are for limited-term financing models in selected sectors of medical technology. Adequate accompanying investigations can document the benefits of innovations and provide patients faster access to them. If we open up the system here, then the health insurance funds will compete for the rapid introduction of innovations in the future.

In summary

If we promote innovations and proceed in a more coordinated manner, while taking greater consideration of quality aspects, then the medtech companies will also remain a growth engine of the health economy for the benefit of patients in 2009.







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

Health Policy

Last year the central topics in health policy were the reorganization of statutory health insurance, the introduction of the health pool as of 2009 and hospital reform.

Further development of the SHI and changes in the medical-technical aids sector

The SHI Competition Strengthening Law (GKV-WSG) of 2007 passed measures which only became effective in the following years. Thus the former National Associations of SHI were replaced by the Central Federal Association of Health Insurance Funds on July 1, 2008 and dissolved as corporations at the end of 2008. The Joint Federal Committee (JFC) was restructured on the same date. A possibility of participating in the now public final meetings was achieved, but the right of experts designated by the industry to have a say in the debate on a case-to-case basis was refused.

The SHI Organization Development Law (GKV-OrgWG) passed after the 2008 summer break made use of the opportunity to amend a large number of provisions in the SHI Competition Strengthening Law by tacking on additional provisions to the bill. A good number of these provisions refer to the medical-technical aids sector, where BVMed had provided important insights and stimuli in many discussions with the political policy makers (see page 10 / 11).

Health pool and Morbi-RSA (Morbidity Risk-based Fund Adjustment)

A new catchword in health policy is the "morbidity risk-based fund adjustment", in short "Morbi-RSA". It complements the health pool, for which the German federal government set the contribution rate in October at 15.5 percent and decided on a reduction to 14.9 percent starting July 1, 2009 with the economic stimulus package passed in January. The Morbi-RSA regulates how the health pool contribution money is distributed to the individual health insurance funds according to the parameters of gender, age, reduced earnings and 80 selected diseases of insurants. The financial consequences lead to enormous insecurity. The health insurance funds are reacting with a consolidation process in order to be able to maintain their positions in the market.

Intensified dialog with policy makers

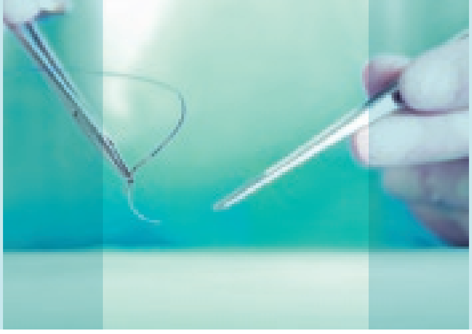
Through regular dialog with politicians from the Bundestag (Lower House of Parliament), the Office of the Federal Chancellor, ministries, states and state representation offices, BVMed is succeeding in reaching the relevant liaisons with its issues and thus incorporating its expertise and the concerns and interests of medtech companies in the current legislative process.

Apart from the established political discussion groups, further consulting committees are becoming increasingly interesting for BVMed: for instance the "Werkstattgespräche Medizintechnik" (Medtech evaluation workshop), working in the steering committee for the Medical Technology Conference, the Health Research Council or collaboration in the program of the Capital Congress. Discussions with the chairmen of committees and associations such as the JFC, the German National Institute for Quality Measurement in Health Care (BQS), the Institute for Hospital Reimbursement (InEK) or the German Hospital Federation (DKG) on the subject of self-governance continually gain in importance for the decision-making process regarding subordinate standards. A new European approach was created last year by launching the campaign "BVMed goes Brussels". Future plans include regular activities and events to address the "German community" on specifically German issues with a European dimension.

Medtech Compass

Another important focus of work is the effective and transparent cooperation betwen industry and medical facilities. BVMed´s Campaign Medtech Compass provides a network between industry and hospital experts in the healthcare compliance sector. Everyone involved in the healthcare market should know what is allowed, and rapidly be able to find contact persons. The new positive and preventive approach of the campaign was presented in extensive discussions, for example with the Ministries of Justice and Health, as well as policy makers from the hospital sector, to further improve the good prevailing conditions in Germany.





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

DRGs / Hospital Financing Reform

Hospital Financing Reform

At the end of 2008, the Bundestag (Lower House of Parliament) passed a law on the regulatory framework for hospital financing, the so-called Hospital Financing Reform Bill (KHRG). The bill provides hospitals with an additional 3.5 billion euros in 2009. It contains an extensive package for improving the economic situation of hospitals, as well as measures aimed at limiting the volume of additional health insurance fund expenditures to this amount in 2009. The financing assistance takes the pay scale increases of 2008 / 2009 into consideration in the state-wide average case value, and provides a job program for nursing staff.

The much-criticized linking of hospital prices to income development of the health insurance funds (link to basic wages) is to be omitted. To this end the German Federal Office of Statistics will determine an "orientation value" by mid-2010 which will record the development of costs in the hospital sector without delay, and replace the strict link to basic wages as of 2011. To what extent this orientation value will actually be applied, however, remains the sole discretion of the German Federal Ministry of Health. The hospital saving premium of 0.5 percent for the rehabilitation of the health funds' budgets will not be extended.

Further development of the DRG system

In order to limit the additional expenditures of health insurance funds for hospital treatments in 2009, a few more amendments were inserted into the German Hospital Financing Law at short notice. The decision has now been made to extend the convergence phase of the DRG system by one year. Compared to the former legal position, which scheduled an expiration of the convergence phase for the end of 2008, the convergence-based additional income for hospitals with budget increases has thus been cut in half. For hospitals with convergence-based budget decreases, these are commensurately cut in half. Restricted to 2009, the hospitals must also grant price discounts to the health insurance funds for services exceeding specifications which were not agreed upon in advance. Such discounts are to be freely negotiated.

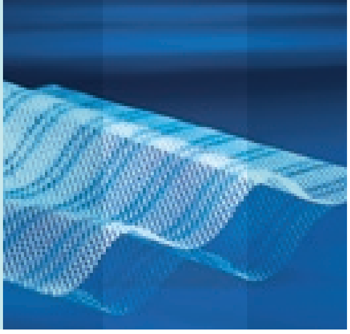
The German Hospital Financing Law also contains provisions regulating the further development of the DRG system. Above all, the prices for hospital treatments are to be equalized throughout all of Germany. Beginning in 2010, different base values valid now in each of the federal states will be gradually converged into a nationwide base rate corridor over a time period of five years. The problem of capital investment backlogs in the hospitals remains unsolved.

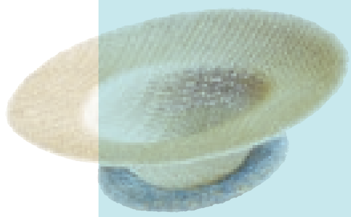
Consequences for medical technology care

In its position statements on the German Hospital Financing Law, BVMed points that if high-quality comprehensive care is to be ensured in the future, hospitals must receive adequate and performance-related financing. The rising cost obstacles on hospitals and budgeting based on basic wages already negatively affect patient care based on innovative medical technologies. There is cause to fear that older generations of technologies will be applied for cost reasons, resulting in suboptimal patient care. The briefly discussed possibilities of selective contracts, which were recently discarded, only open the door to price dumping and thus an associated declining healthcare quality with high-grade medical technologies.

Campaign "Fortschritt erLeben"

The campaign "Fortschritt erLeben" meaning "Experience progress" (*www.fortschritt-erleben.de*) aspires to establish a mid-term framework for more reliable reimbursement conditions for innovative medical technology services in the German DRG system starting in 2009. In the DRG system, the reimbursement schemes for new examination and treatment methods were included in the hospital remuneration law. This provides a statutory framework which allows hospitals to employ new examination and treatment methods (NUBs) that are not yet described in the DRG catalog. In practice, the provisions and implementation have proven to be too rigid and bureaucratic so far. BVMed advocates greater flexibility. The amendment passed with the German Hospital Financing Law now replaces the previously rigid time framework and gives hospitals more flexibility in applying to the health insurance funds for reimbursement of innovative patient services.





Hernia mesh and plug for hernia care

Health Technology Assessment (HTA)

From the industry's point of view, technology assessment is correct and necessary. But we need unambiguous and objective directives on what should be assessed and how the assessment is to be conducted. If technology assessment is to provide all patients prompt access to the medically and economically appropriate therapies, the system must be transparent and open. It has to allow all participants to contribute to the decision-making process and promote prompt action through deadlines. The HTA position paper from 2008 of the European umbrella association EUCOMED, supported by BVMed, should contribute towards clarifying and harmonizing the methodological approaches for assessing medical technologies across Europe from the viewpoint of the companies. Aspects such as the purpose and goal of HTAs, participations, transparency and standards of evidence are discussed.

Health Technology Assessment (HTA) – hard but fair?

In a conference on technology assessment organized by BVMed with experts from scientific institutions, health insurance funds, HTA institutions and the medtech industry, the participants arrived at the following estimations about further developments:

> HTA reports can help provide clearer evidence of medical and economical benefits of a medical technology innovation to the policy makers.
> HTA is concerned with the effectiveness, commensurability and costs of technologies and focusses on the central issues: Is the technology beneficial? If yes, for whom and at what cost compared to the alternatives?
> In HTA reports and requirements on studies, medical devices are by no means to be equated with pharmaceutic products. Medical devices are much more heterogeneous. A sufficient differentiation of the assessment methods is therefore necessary. Moreover, gradual developments and process innovations also play a large role.
> Problems can arise with the early assessment of medical devices, since the user plays a large role in new medtech procedures and has to first become acquainted with the new method.

The upshot of the conference: The systematic and transparent evaluation of medical technology innovations is an important challenge for companies in the medtech sector. The medtech companies must now develop HTA strategies, since the CE marking will not suffice for the reimbursement of medical devices in certain areas over the medium and long term.

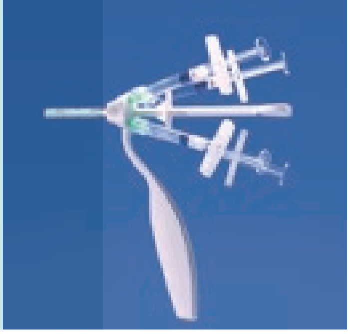
Assessment of benefit of medical technologies

The Institute for Quality and Economic Efficiency in Healthcare (IQWiG) has provided a method paper as basis for discussing the assessment of benefits and costs in the German statutory health insurance system. In its position statement on the method paper, BVMed points out that the assessment of benefit of medical technologies is not possible in the form of randomized clinical studies, or only possible under certain conditions. Moreover it is advisable to collect cost data under everyday conditions. The method of such an assessment must also be transparent to allow for reasonable participation of the medtech industry in the process.

Outcome Research

BVMed is actively participating in the discussion of how to structure and further develop the necessity of outcome research. Supported by BVMed, the Outcome Research Congress 2008 was conducted by the German Outcome Research Network (Deutsches Netzwerk Versorgungsforschung). The congress also produced a position paper on the status of outcome research from the point of view of the medtech sector.


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 2007 healthcare reform (SHI Competition Strengthening Law) aimed at achieving savings of 300 million euros in the medical-technical aids sector. Considering the current price trends in the medical-technical aids sector, with price reductions of over 50 percent, this goal should already be surpassed by now. Things look differently in actual practice. In fact there has been a slight rise in expenditure. This increase can be primarily attributed to an increase in quantity due to demographic developments.

Implementation and consequences of the 2007 SHI Competition Strengthening Law

The consequences of the SHI Competition Strengthening Law were especially noticeable for patients, care providers and manufacturers in 2008. Aside from the market selection and strong collapse of prices, invitations to tender as first contract option for the health insurance funds resulted in a deterioration in healthcare quality for affected persons. Users of technical aids who wanted to retain their customary quality were forced to add private supplementary payments.

The loss of the old approval brought an enormous challenge, as care providers had to sign contracts with each relevant health insurance fund by the end of 2008, since provisioning the patients will only be possible as contract partner starting January 2009. Already by the middle of the year, there were signs of insecurity and anxiety from all sides of those affected by these regulations. There were many legal ambiguities which had to be clarified as quickly as possible. Furthermore, it became clear that the health insurance funds would not succeed in achieving a country-wide contract landscape by the end of the year. In fact, experts assumed that a maximum of only 50 percent of the technical aids market is regulated under contract.

SHI Organization Development Law (GKV-OrgWG)

In order to ensure future healthcare quality and a diversity of healthcare providers under fair conditions of competition, modifications to the amendments of the SHI Competition Strengthening Law were urgently required. With numerous position statements and ongoing constructive and continuous discussions with all parties involved, companies in the technical aids sector have succeeded in pointing out the deficits of the new regulations and arrange for the necessary amendments in the SHI Organization Development Law. The following amendments were achieved:

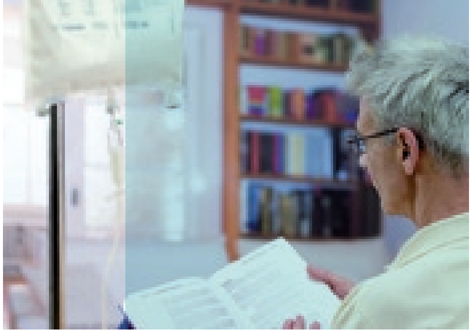
- Introduction of a uniform prequalification procedure with conclusive character;
- Right of information and accession right to contracts according to Article 127 Section 2 Social Security Code Book V for all qualified healthcare providers;
- Extension of the genuine transition period to December 31, 2009, if there are no invitations to tender according to Article 127 Section 1 Social Security Code Book V;
- Transformation of the “must” rule advisory provision into a “can” rule discretionary provision regarding execution of invitations to tender according to Article 127 Section 1 Social Security Code Book V.

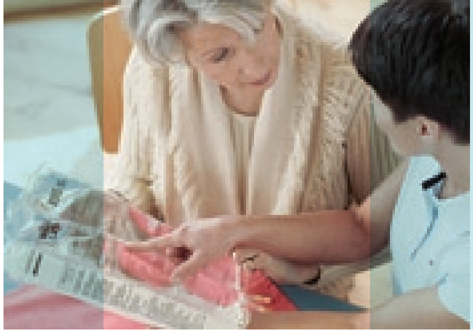
Another success, especially for the care providers, is the legally anchored right to influence the stipulation of prequalification procedure and the definition of the practicability of invitations to tender. The law has now transferred these tasks jointly to the SHI Central Federal Association and the leading central organizations of healthcare providers on a federal level. This way the central organizations of healthcare providers are equal negotiating partners of the health insurance funds for the first time.

Action league “My choice!” (“meine Wahl!”)

BVMed also supports the action league “My choice!”, a union of handicapped people, self-help associations, technical aid manufacturers and healthcare partners. Currently there are 79 comrades-in-arms (*www.buendnis-meine-wahl.de*). The action league advocates the right of those affected to have a say in the provision of medical-technical aids. The goal is to ensure care with medical-technical aids that corresponds to state-of-the-art technology.


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

Homecare is still considered a growth market with a good future. Nevertheless, the sector is caught in the controversy between the continually growing demand by an increasing number of persons in need of care on the one hand, and the enormous cost pressure of statutory health insurance schemes on the other. The greatest challenge in 2008 was managing the topic of competitive bidding (invitations to tender). The health insurance funds as well as the healthcare providers had to tentatively “grope their way” towards using this instrument. The different standards for implementing the new regulations led to insecurity within the entire market. The consequence has been numerous complaints and the resulting associated pending legal procedures in court and with the awarding offices.

The quality of medical care has played a subordinate role in the awarding documents until now. But in order to systematically implement increased quality competition in the medical-technical aids sector, the healthcare or service aspect must be shifted more to the foreground. It is therefore urgently necessary for the National Associations of SHI to prepare the minimum standards for the supply of technical aids prescribed by law and establish them in the medical-technical aids register. BVMed offers its support in this endeavor and will continue its discussions with the health insurance representatives.

Invitations to tender and the experience of the homecare sector

Despite the ongoing legal procedures and all existing insecurities, in 2008 the health insurance funds increasingly solicited for tender, especially in the sector of absorbing incontinence care products. There were approximately 30 invitations to tender by the end of the year. The German SHI Organization Development Law (GKV-OrgWG) effective as of January 1, 2009 now brings new changes for all participants in the homecare market. In the future the health insurance funds may choose how they want to find their contract partners. It is no longer a binding obligation to solicit tenders. However, this regulation will hardly be able to slow down the collapse of prices. It also remains open to what extent the focus will turn to the quality of care in the future.

Public relations – strengthening of homecare

In 2008, BVMed organized the Homecare Forum at the Geriatric Care 2008 trade fair in Hanover and the Technical Aids Forum at the REHACARE in Düsseldorf. The talks given by experts, lively podium discussions and exchange of information among all participants made the event a complete success It will be continued in 2009.

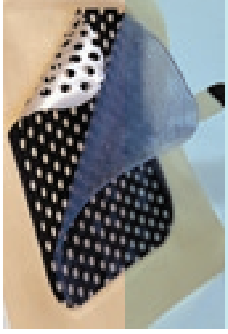
Electronic Health Card

The introduction of the electronic health card is a topic of some significance to homecare companies. As homecare can involve technical aids, dressings and drugs, 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. Hitherto the eprescription has been confined to pharmacy-only drugs. For the care providers it is important that they be connected to the telematics infrastructure at an early date, and that the electronic health card takes into account the particularities of the homecare sector. The regional testing of the electronic health card is taking considerably more time than originally expected. So far, the homecare providers have not been integrated into the field tests. The electronic Health Professions Register (eGBR) is under construction.

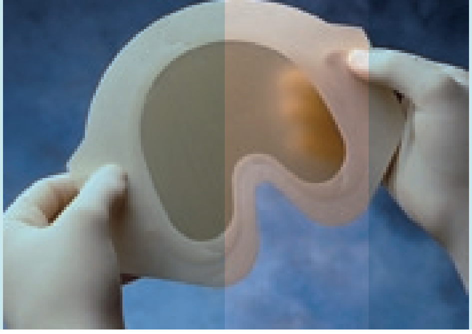
New models of care

In Germany, there were 5,895 contracts for integrated care with a reimbursement volume of 819 million euros in 2008. These are the current figures from the German National Institute for Quality Measurement in Health Care (BQS). 128 of the concluded contracts apply on a national level. The start-up funding ended on Dec. 31, 2008. As a consequence, there will likely be a number of contracts which will not survive without this financing and therefore become invalid. The others must become more economically viable on their own. Thus the companies in the Medtech industry might have to restructure their distribution channels, protect themselves from other risks and take advantage of new opportunities in order to survive in a changed market.

Wounds must be attended!
Modern foam dressing



Electrostimulation in woundcare



Hydrocolloid woundcare dressing

Medical Devices Act

MDD Recast

The EU Commission conducted an internet "consultation" of the expert groups between May and June 2008 with the purpose of determining whether, and if applicable how, the European regulatory framework can be revised for medical devices. The consultation was met with incomprehension by the industry as well as the offical authorities because of its early date, since the Amending Directive 2007/47/EC had only come into force on October 11, 2007, which had led to a drastically more rigorous regulatory environment for the medtech industry. The consultation focussed on proposals for revising the regulatory framework for the notified bodies, clinical trial requirements, questions concerning vigilance and market surveillance of medical devices, and questions on the transparency of manufacturers and product information. The EU commission suggested to grant the European Medicines Evaluation Agency (EMEA) new official monitoring responsibilities of (as yet non-specified) medical devices "with high risk" excluding the notified bodies, which was generally rejected by the expert groups after evaluation of the consultation. The industry and regulatory authorities justifiably fear a development of "pharmaceutical juridification" of the law governing medical devices. The German associations of the medtech industry, represented by BVMed, applied to Günter Verheugen, the responsible EU commisioner and Vice President of the EU commission, with a request to postpone the pending new revision of the Medical Devices Act concerning the "MDD Recast" for at least two years. First of all they want to wait to see what the impact of the Amending Directive 2007/47/EU will be in practice, which applies nationally only after March 21, 2010. EU Commissioner Verheugen replied to BVMed on January 9, 2009 that his impression was that "the thorough preparation of the project requires more time and a proposal still seems premature in 2009". He invited BVMed to a meeting to discuss the current challenges of the medical device sector.

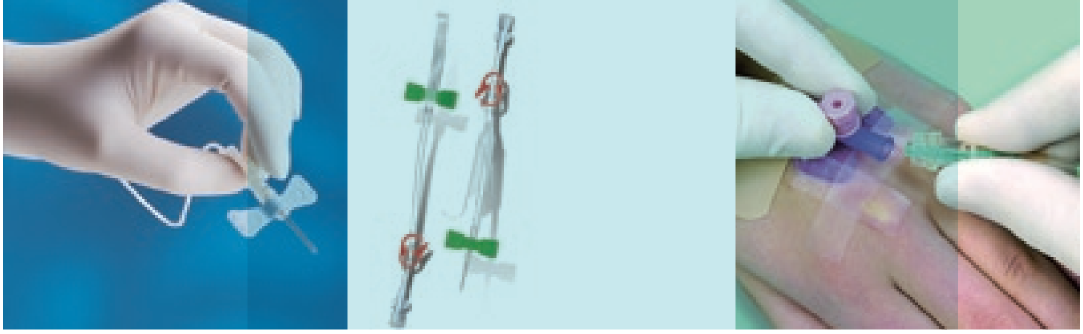
New Approach Review

In June 2008 the European Parliament and the EU Commission created a new regulatory framework ("New Approach Review") to adjust the legal requirements of the 26 sectoral EU harmonising directives, including the three master regulations for medical devices. This includes all EU regulations which substantiate industrial products bearing the CE marking to express their free marketability within the EU market. The legal act helps to reorganize the accreditation of notified bodies in Europe, create a uniform regulatory framework for conducting national market surveillance, improve the control of imports from EU third party states and protect the CE marking from counterfeit or deception. The "New Approach Review" has special national impact on Germany, since the German accrediting system must be reorganized by December 31, 2009. The Accrediting Body Establishment Act prescribes that starting January 1, 2010 only one body shall conduct all accreditations in Germany.

Fourth Amendment to the Medical Devices Act (MPG)

On December 18, 2008 the German Federal Ministry of Health submitted a draft of a "law to amend medical device law regulations" (4th MPG amendment). On the one hand, the amendment assists the unspectacular national implementation of the 2007/47/EU directive. Furthermore, it indicates a clear trend towards national bureaucratization and adjustment of the Medical Device Law to the German Pharmaceutical Law.

The proposed governmental mandatory approval required for conducting clinical tests with medical devices by the BfArM (Federal Institute for Drugs and Medical Devices) and the proposed prohibition of private contract ethic committees has been unanimously rejected by the industrial associations. Various suggestions offered by BVMed for improving the reporting system, for instance the introduction of a "Vigilance Officer" in hospitals, were also not taken into account in the draft. In the Medical Devices Operator Ordinance, the law has not ventured to offer a legal definition of "operator". This could lead to "second-class safety" depending on whether the patients use a product of the health insurance funds or something else. Another unresolved issue remains the question whether and under what conditions the processing of medical single-use devices is legally permissible.



Preventing pinprick injuries with safety products

Patient and User Safety / Environmental Issues

Preventing hospital infections

Every patient has the right to be protected against nosocomial infections. In Germany, this claim is opposed by 500,0000 to 800,0000 cases of hospital infections per year. Apart from prevention strategies and training sessions, the proper use of innovative medical devices can make a significant contribution to reducing these infections. In collaboration with hospital hygiene experts, BVMed is actively engaged in explaining the contribution of medical technologies in the prevention of hospital infections and accelerating the application of hygiene-relevant technologies. BVMed hopes to establish a permanent forum of experts which deals with concrete topics involving all aspects of hygiene and medical devices on a case by case basis.

User safety through safe instruments

Injuries caused by cutting, pricking, and scratching with potentially infectious instruments, so-called “sharps injuries” (injuries caused by pointed or sharp instruments), should be avoided by using safe instruments. This is prescribed by the German Technical Regulations for Biological Substances at Work (TRBA 250), whose requirements were tightened in the new version issued in February 2008. According to these regulations, it will be increasingly difficult to abstain from using safe instruments. With the help of a nursing educator, the BVMed sectoral interest group “Sharps injuries prevention” has now developed a modular set of learning-units which will provide healthcare instructors with comprehensive teaching material about the causes and possibilities of avoiding sharps injuries. Thus a contribution is made towards preventing infections of the nursing staff caused by sharps injuries through implementing measures at the root cause by training future users.

Reuse of Medical Devices

In spring 2008 the Federal Ministry of Health (BMG) submitted its “Field report on the processing of medical devices in Germany”. The report concludes that the prohibition of reprocessing medical single-use devices frequently demanded by the manufacturers is not required. Instead, enabling ordinances are to regulate the stipulation of concrete requirements on medical device processers and prescribe their certification via the 4th amendment to the Medical Devices Act (MPG). A significantly more critical view than the Ministry’s assessment is expressed in the summary of the EU survey on the reuse of medical single-use devices likewise conducted in 2008, which expresses explicit concern about a possible health hazard.

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

The new European chemicals legislation REACH also became palpable for BVMed members in 2008: From June 1 to December 1, 2008, manufacturers were able to pre-register materials and thus get an extension of deadlines until achieving the required and considerably more complex registration. Materials which are not pre-registered or registered may no longer be placed on the market. The first “list of candidates” of substances of very high concern was published on October 28, 2008. Since then, manufacturers of products, including medical devices, must inform their customers of the presence of these materials in their products if they make up more than 0.1 percent of the product.

In early 2009 the first “priority materials” to receive approval were proposed. DEHP, the proven plasticizer in a multitude of medical products, is included in the list of candidates as well as under “priority materials”. BVMed advocates an adequate interpretation of the REACH requirements und has informed its members about the requirements and possibilities for implementation. Effective as of January 1, 2009, the 5th amendment to the Packaging Ordinance with nine dual systems and the increased requirements on sector specific solutions and required documentation has changed the prevailing conditions for the disposal of packaging. Packaging from hospitals can continue to be disposed through dual systems. In practice, however, it appears that at the beginning of the year 2009 the free of charge collection of waste packaging from hospitals has still not been satisfactorily solved. The revision of directives about reduction of hazardous substances (RoHS) in electrical and electronic appliances and waste electrical and electronic equipment (WEEE) to be (RoHS) adopted in 2009, will surely bring along new requirements for the manufacturers of affected medical devices.

BVMed media seminar in Berlin

Communications / Press

Most successful year for communications work of BVMed

2008 was the most successful year of media work for BVMed since the association was founded. A total of over 1,000 articles on related medtech topics appeared in various print and online media. With 470 printed articles citing BVMed, a range of 30.6 million readers was reached.

In the online sector, 268 articles mentioning BVMed were placed, with 162 direct links to the BVMed website. These online articles had some 78 million individual visits and 523 million page impressions. In addition there has been an extremely positive media resonance to various BVMed information campaigns. The patient initiative “Aktion Meditech” got 145 contributions reaching 44.6 million people and contacts amounting to a total of 117 million readers, predominantly in public media. The campaign “Meine Wahl” (My Choice) was able to get 104 contributions and achieve a print run of 2.6 million. And finally, the BVMed campaign “Medtech Compass” placed 30 contributions in relevant professional journals on the topic of healthcare compliance.

Information service expanded

BVMed media efforts with press releases, press seminars, editorials and professional articles were expanded by the background format “Media dialog” in 2008. The supply of information is supplemented by weekly newsletters to over 7,200 subscribers and various e-mail services as well as 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 medtech sector’s image, BVMed carried out further projects, such as its own booth at the Capital Congress in Berlin in 2008 or the seventh BVMed media seminar in October 2008.

Annual communications congress

The developments in the medtech industry are keenly followed by the public. Physicians and health insurance funds as well as patients want to be informed about new methods of treatment. Politicians and the media are increasingly interested in medtech as an important sunrise industry. The annual “Communications Congress Medical Technology” wants to sensitize the industry for the challenges ahead and strengthen its communication efforts. The fifths congress will take place on June 9 – 10, 2009 in Cologne and offer numerous case studies, journalist reports and workshops.

BVMed Website with new layout and expanded film offering

The BVMed website at *www.bvmed.de* has appeared with a new layout and more online film material on modern medical technologies since spring 2008. The core element is the integration of interactive offers such as film material, ordering possibilities and conferences in content-related context. Apart from the website, the Extranet was also adapted to the new look.

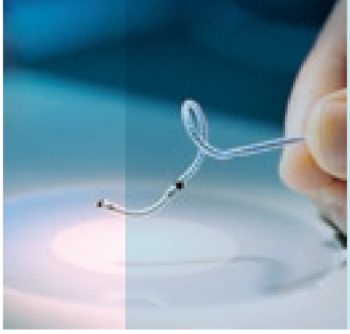
TV Service Medical Technology

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. Seventeen film projects have been completed by now, most recently on neurosimulation and the provision of hearing aids. Broadcasts have appeared on over 30 different TV news shows viewed by over 12 million people. Added to this are some 3,000 DVD orders. BVMed plans to develop further formats and a greater integration of online media in 2009.

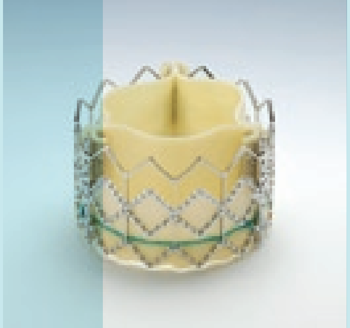
PR campaign “Aktion Meditech”

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. Apart from intensive media work, activities consisted of an annual patient group symposium, media seminars, four so-called “Berlin Talks” 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*.

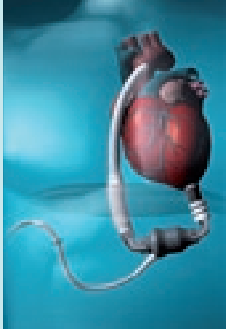
Medical technologies in cardiology: Pacemaker for cardiac resynchronization therapy (CRT)



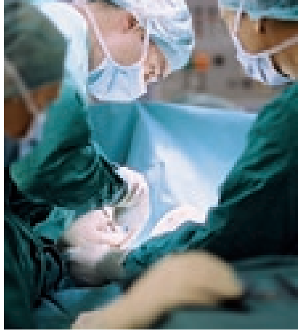
Electrode for cardiostimulation



Cardiac valve replacement (pulmonary valve)



Implantable cardiac support system



Use of a cardiac pacemaker system in surgery

Reports from BVMed's Expert Committees

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 continual 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 or restricted basis which provide the board and management with expert support in a specific field.

A complete list of BVMed Expert Committees is provided on the internet at *www.bvmed.de/wir/Arbeitskreise_Fachbereiche_und_Projektgruppen/*

FOCUS GROUPS

Focus Group "Legal Issues" (AKR)

The AKR cooperates and holds meetings with 18 external members of the network "Medical Device Legislation", a group of lawyers specializing in medical device law. 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, soon featuring some 250 court rulings on medical devices. In May 2009, the group conducted the fourth annual BVMed symposium on "Current legal issues pertaining to medical devices".

Focus Group "Regulatory and Public Affairs" (AKRP)

The current key issues of this focus group include the implementation of the 2007/47/EC Directive and the expected legal changes accompanying the 4th amendment to the Medical Devices Act (MPG), including the topics: clinical evaluation of medical devices, reporting of incidents and the introduction of the "electronic" or "alternative" labelling of medical devices. The AKRP is in charge of editing the 10-part BVMed information series on the Medical Device Legislation

Focus Group "Environment" (AKU)

Different sub-groups are organized under the AKU umbrella. AG REACH is concerned with the actual obligations stipulated by the new EU legislation on chemicals for the manufacturers of medical devices. The main focus areas were the treatment of drugs / medical device combinations, recommendations for pre-registration of materials, listing possibilities for informing customers about materials on the list of candidates, and discussions regarding the obligation for authorisation with regard to medical devices.

SECTORAL INTEREST GROUPS

Sectoral Interest Group "Eye Surgery" (FBA)

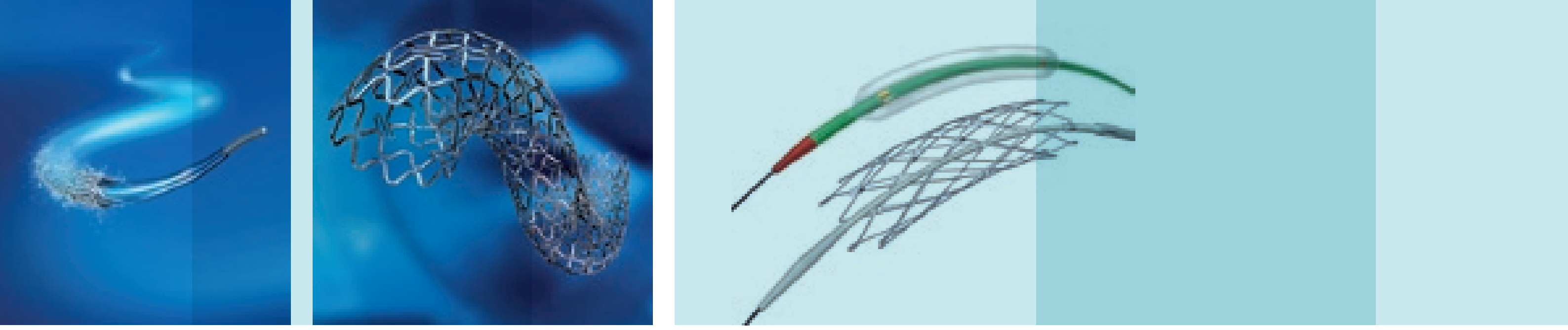
The Sectoral Interest Group "Eye Surgery" accompanied the start of the information campaign "Initiative Grauer Star" (cataracts initiative), which informs about "innovative solutions through modern artificial lenses".
In 2009, measures will focus on communication via the pharmacies as well as establishing a consulting telephone service. Another emphasis of FBA activities is the further development of its financing model to supply patients with high-grade intraocular lenses, which currently are only reimbursed in exceptional cases.

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, and its members act as liasons to the public authorities.

Sectoral Interest Group "Brachytherapy" (FBBT)

FBBT's working group "Interstitial Brachytherapy" (PG IBT) promotes the admission of the seed-method for prostate cancer into the reimbursement catalog for office-based outpatient care. The application to admit it to the outpatient reimbursement catalog is currently pending at the Joint Federal Committee (JFC).



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

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

The FB DRG accompanied the discussion on the Hospital Financing Reform and developed position statements on the complex legislative process. The FB DRG furthermore coordinates the DRG applications and the classifications (ICD, OPS) in BVMed. It developed a line of argument for the budget negotiations concerning medical devices and created concepts for further training seminars.

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 medicine, and their implementation in the pertinent standards. The sub-group “Communication” (AGK) of manufacturers of first-aid kits for cars continued its 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 is concerned with the diverse regulatory requirements on the ethylene oxide sterilization of medical devices. The relevant regulatory framework includes the Medical Devices Act, the Biocidal Products Directive and the EU Chemicals Regulation REACH.

Sectoral Interest Group “Trade / Homecare” (FBHH)

Due to the amendment of the charter of BVMed passed in the spring of 2008, trade companies have now also become completely integrated in BVMed. The goal is an intensive dialog between industry and trade companies and a stronger utilization of synergy effects. So far, 12 formerly associated companies have opted for full membership in BVMed and for collaboration in the FBHH sectoral interest group. The group works closely with the already existing sectoral interest group “Homecare”.

Sectoral Interest Group “Health Technology Assessment” (FB HTA)

The FB HTA developed position statements for HTA institutions such as the Institute for Quality and Economic Efficiency in Healthcare (IQWiG) or the JFC. The group moreover coordinates the BVMed participation in the HTA Board of Trustees at the German Institute of Medical Documentation and Information (DIMDI) and supports concepts for seminars and conferences on HTA topics.

Sectoral Interest Group “Homecare” (FBHC)

The FBHC revised the Homecare information brochure and represents Homecare as part of outpatient care. At industry-relevant get-togethers such as the REHACARE or the Geriatric Care trade fair, the benefits and quality of homecare were discussed with various market participants in medical care (health insurance funds, healthcare providers, nursing staff).

Sectoral Interest Group “Infusion Therapy” (FBIV)

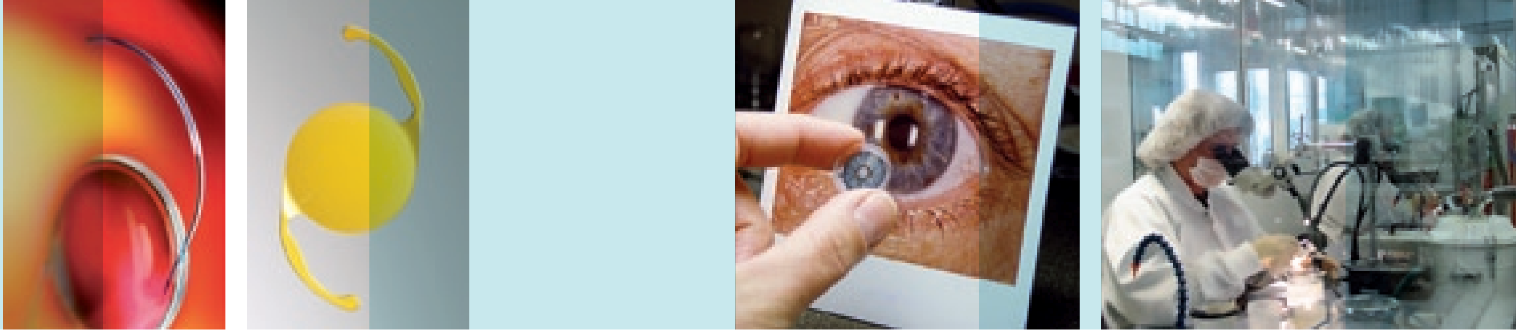
Due to the product developments and modified legal requirements, the quality standards of the PG 03 (application aids) in the medical-technical aids register must be urgently revised. This sectoral interest group prepared a proposal for restructuring product group 03 based on the particular areas of care (parenteral feeding, chemotherapy, pain therapy, etc.). An initial joint discussion with health insurance funds and the MDS (Medical Review Board of the SHI) had already taken place.

Sectoral Interest Group “Cardiac Medical Devices” (FBKMP)

Sub-groups of the FBKMP cover special areas of products for the cardiovascular system: active implants (cardiac pacemakers, ICD-CRT systems), interventional technologies (stents) and cardiosurgical interventions (heart valve technologies, cardiopulmonary systems). The group also supports a database for active implants (*www.herzstimulation.de*).

Sectoral Interest Group “Artificial Feeding” (FBKE)

The entitlement to medical food for enteral feeding will be regulated by § 31 Section 5 Social Security Code Book V in the future. The FBKE developed a position paper in the legislative process and created a patient information sheet about the new provisions. Furthermore the FBKE



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

worked with the Dietetic Association to develop an information sheet explaining the distinctive aspects of using disposable syringes for administering nutrition by tube feeding and rinsing the tubes. The sectoral interest group contributed to the creation of the QVH standards for the enteral feeding sector and helped organize the Palliative Care Forum to be held at the Geriatric Care trade fair in Nuremberg in spring 2009.

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

The FBLL works on legal questions of health insurance reimbursement. Here the bidding / tendering law plays an increasingly important role. The FBLL is also concerned with the implementation and consequences of the SHI Competition Strengthening Law. The group actively participated in creating the position statement to the SHI Organization Development Law (GKV-OrgWG).

Sectoral Interest Group "Medical Technology Implants" (FBMTI)

The FBMTI represents the manufacturers of artificial joints. It supports the introduction of an endoprosthesis register with the assurance of providing a manufacturer reference database and sending two experts to join an appropriate task force which has developed a concept for the JFC. Another main agenda item was creating a new trade fair concept to establish a collaboration of expert societies, trade fair firms and manufacturing companies on a new basis. The goal is to further raise the quality and efficiency of medical congresses for the exhibiting companies.

Sectoral Interest Group "Modern Wound Care Products" (FBMW)

The FBMW has developed four explanatory modules for the prescriptability and reimbursability as well as cost effectiveness of hydroactive or modern wound care products: 1. The brochure "Cost effectiveness and health policy – use of hydroactive wound dressings". 2. The chapter on dressing materials in the yellow list, a medical directory. 3. The annual information event on "Hydroactive wound care". 4. Training sessions conducted with the association of medical skilled professions.

Sectoral Interest Group "Sharps Injuries Prevention" (FBNSP)

The FBNSP unites suppliers of safety instruments to protect from injuries caused by cutting, pricking, and scratching during medical daily practice. The main focus was the completion of a comprehensive set of teaching materials for teachers in nursing classes. The materials are to be distributed to nursing schools in 2009. Other topics discussed were the "Technical Guideline for Biological Substances at Work (TRBA 250) as well as the standardization of safety instruments.

Sectoral Interest Group "Renal Replacement Therapy" (FBNE)

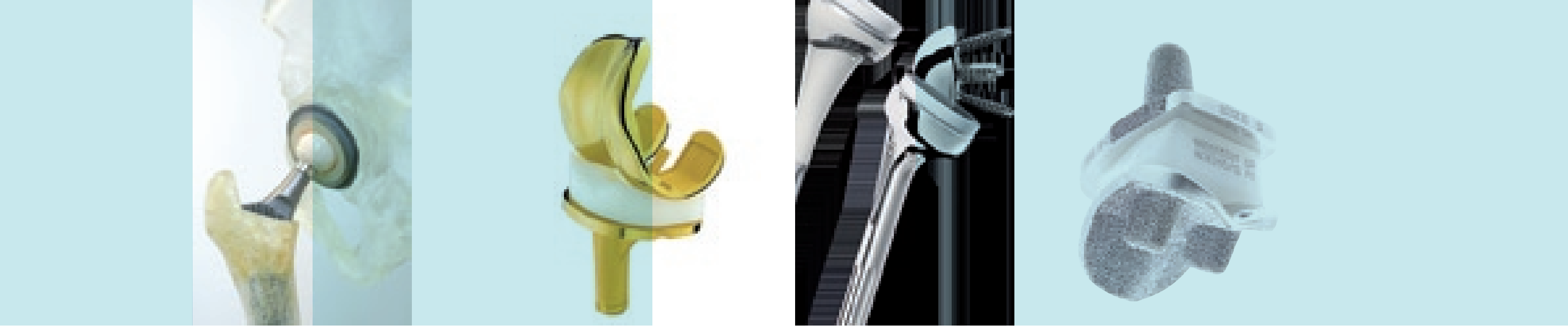
With the initiative "Kidney Alliance", suppliers of products for dialysis have set the goal of informing and educating the public about the status of these life-sustaining medical technologies and their prevailing conditions. The initiative "went public" for the first time in 2008 with a series of measures. The success story of dialysis therapy in Germany is described in a brochure entitled "More than just surviving". A newsletter entitled "Dialysis" appeared as special edition of the successful PR campaign "Action Meditech". A website and press relations work supplement the program.

Sectoral Interest Group "Peripheral Vascular Medicine" (FBPG)

The FBPG supports the promotion of medical technologies in the peripheral vascular system, such as PTA technologies or occlusion systems. Under the coordination of BVMed, the group also participates in the maintenance and evaluation of the scientific register "PTAREG", which records the treatment of patients suffering from peripheral occlusive arterial disease before or after undergoing PTA. They help support continued education at professional congresses on innovative technologies as well.

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

The activities of the FBI-H concentrate on the necessary contents for competitive bids, such as taking respective quality standards into consideration and the appropriate separation of bids for the outpatient and inpatient sector. The FBI-H has conducted six Roundtable Discussions



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

with the responsible nursing home operators and health insurance funds. Another important topic handled by the group is the further development of the general conditions in the technical aids market.

Sectoral Interest Group “Soft Tissue Repair Implants” (FBSTRI)

The new sectoral interest group represents the interests of suppliers of implants to reinforce soft tissue such as hernias or ligaments. The goal of the new BVMed sectoral interest group “Soft Tissue Repair Implants” is to discuss the common interests and necessities for this type of product across companies, and to coordinate resulting activities, for example regarding reimbursement questions and quality aspects. There is need for action here in the inpatient as well as the outpatient sector.

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

The FBSRV pursued an intensive discourse with the state pharmacy associations concerning developments in the market for dressing materials and practice supplies in order to effectively further develop this market. Another topic deals with the consequences of the new uniform reimbursement catalog (EBM) on the reimbursement and prescription of medical material supplies in the SHI physician sector.

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 FBEO (“Ethylene Oxide Sterilization”) and FBS (“Radiation Sterilization”).

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

The FBSI advocates patient-oriented and economical care to ensure the healthcare quality for ostomy patients and incontinent patients in the long term. Binding minimum quality standards and their inclusion in the medical-technical aids register play a large role here. The FBSI actively contributed to the position statements on the SHI Organization Development Law (GKV-OrgWG) and at the BVMed Homecare Forum at the Geriatric Care 2008 trade fair.

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 relevant laws and regulations, and disseminating explanatory information about the importance of radiation sterilization.

Sectoral Interest Group “Therapeutic Apheresis” (FBTA)

The sub-group “Lp(a)” produced a detailed position statement on the assessment of apheresis treatment for a rise in isolated Lp(a) by the “Gemeinsamer Bundesausschuss” (G-BA). In June 2008 the G-BA decided to include the method under SHI care. A novelty is that the G-BA linked this decision with the demand that healthcare providers conduct a prospective controlled study concerning the method by latest 2009.

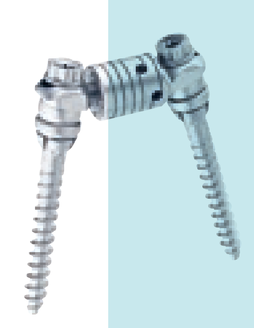
Sectoral Interest Group “Tracheostomy / Laryngectomy” (FBTL)

The FBTL advocates the establishment of minimum care standards to secure an individual patient care of laryngectomized and tracheotomized patients in the long term. Other important topics are current billing problems, the delegability of changing tracheal tubes to non-physician staff and the modifications made to the medical-technical aids register.

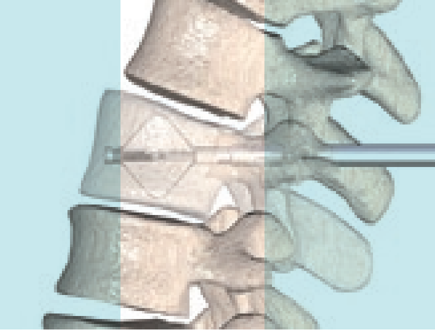
Sectoral Interest Group “Spine Surgery” (FBSC)

The FBSC worked for a third year on further developing the coding guideline for the DRG system in cooperation with the relevant medical expert societies. Moreover, the sectoral interest group supports collaboration with the relevant medical experts groups to include spine technologies.

Artificial intervertebral disk replacement



Spinal implant



Treatment of a vertebral body fracture

WORKING GROUPS AND SUB-GROUPS

Working Group "Decubitus Forum" (DF)

The DF developed a position statement on the current invitations to tender in the decubitus sector and published numerous articles. The forum created a special information flyer for patients. In addition, a guideline for reprocessing anti-decubitus products was published.

Working Group "Hospital Sales" (PG PAK)

Invitations to tender and buying cooperatives have fundamentally changed purchasing transactions between industry and hospitals. The new PG PAK will form a communications platform to develop common goals and strategies in the procurement process.

Working Group "Electronic Health Card" (PG eGeK)

The group prepared a proposal for the assignment of health professional cards to other types of care providers and the providers of medical supplies. Now an actual technically feasible concept is to be created for this application process and the procedures of the healthcare providers in a joint workshop with a trust center. Furthermore the working group is involved in an intensive exchange with the Federal and State Working Group, which is occupied with the introduction and implementation of an electronic Health Profession Register and its financing.

Working Group "PVC" (PG PVC)

The most important theme of the PG PVC concerns the statutory regulations and requirements involving all aspects of the plasticizer DEHP. After the amendment of the Medical Devices Directive from 2007, certain medical devices containing DEHP must labelled as such starting March 2010. According to the REACH regulation, since October 2008 manufacturers have already been obliged to inform their customers if their products contain more than 0.1 percent DEHP.

Working Group "Reuse" (PG Reuse)

The "Reuse" working group is concerned with the reprocessing and reuse of medical devices. The main topic was the "Field report on the processing of medical devices in Germany" submitted by the Federal Ministry of Health. In its position statement to the 4th amendment to the Medical Devices Act (MPG), BVMed advocates that patient protection should be taken more into account in the reprocessing of medical devices.

Working Group "Material Costs and Outpatient Surgery" (PG SAO)

The working group coordinates proposals for the inclusion and financing of medical technologies in the service catalog for outpatient surgery by hospitals and office-based physicians or small private clinics. An intensive dialog is being conducted with representatives of the contract partners and users about the proper representation of technologies.

Working Group "Tissues" (PGT)

PGT focuses on products made by using animal or human tissue, cells or blood, viable or non-viable. These products are not always subject to medical device legislation. PGT deals with loopholes and borderline questions.

Sub-group "E-Standards" (AGE)

The sub-group "E-Standards" represents companies in the "Forum eStandards". This forum, a committee made up of representatives from hospital organizations and medical technology companies, considers itself a strategy group for questions on information and communication standards involving all aspects of purchasing, delivery and application of medical devices. With its 11th E-Health conference in February 2009, BVMed established an "E-Procurement get-together" and an information and communication platform for hospitals, manufacturers and service providers. The conference focused on the standardization of processes and catalogs, the significance of auto-ID systems and the current state of the E-Procurement platforms.

Sub-group "Catheter-related infections" (AG Katheter)

This sub-group communicates the contribution of innovative medical devices to reduce infections in medical facilities. In May 2008 a meeting was held with leading hygienists from hospitals as well as the Robert Koch Institute to figure out cooperation possibilities for preventing hospital infections.

BVMed's Head Office in Berlin

In dialog with policy makers:
Member of the Bundestag Dr. Hans-Georg Faust (left) with BVMed chairman of the board Dr. Meinrad Lugan
Director General Joachim M. Schmitt with State Secretaries Dr. Hartmut Schauerte (Ministry of Economics)
and Dr. Klaus Theo Schröder (Ministry of Health)

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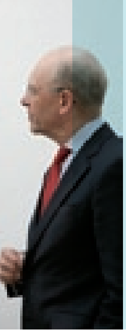


BVMed's "Health Talks" with Joint Federal Committee chairman Dr. Rainer Hess

BVMed – Our Services for You

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

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 on page 15. 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 circulars to all members, specific circulars for the individual Expert Committees, weekly newsletter, weekly chartpool, monthly report, Extranet for member companies.

EXTERNAL COMMUNICATION

Website at *www.bvmed.de*, brochures, information cards, BVMed special events, MedInform conferences, training seminars (medical device consultants, SHI training, workshops on bidding/tendering law and CRM topics), press releases and conferences, press seminars, TV service with film material, background discussions with the media.

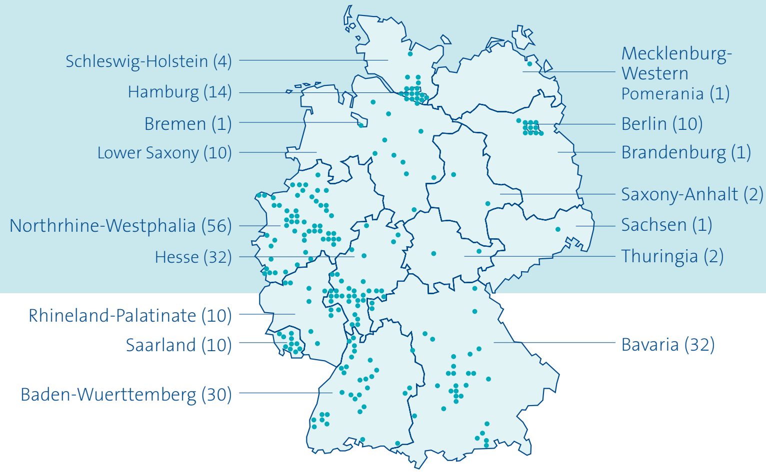
4. Representation

BVMed represents the interests of the medical technology sector. Important aspects of this work include political marketing and one-on-one interviews, the maintenance and support of networks, parliamentary discussion evenings, background discussions, participation in parliamentary hearings as well as representation in committees, advisory councils, 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 2009: 216 members – current list available at *www.bvmed.de*

BVMed Membership List

1

*1stQ Deutschland GmbH & Co. KG

3

*3M Medica Zweigniederlassung der 3M Deutschland GmbH

A

aap Implantate AG
*Abbott GmbH & Co. KG
*Abbott Vasculare Devices
Abena GmbH
*Abiomed Europe GmbH
AcriTec GmbH
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AMOENA GmbH & Co. KG Medizin-Orthopädie-Technik
Andreas Fahl Medizintechnik-Vertrieb GmbH
*Ansell GmbH
ArthroCare Deutschland AG
ASSAmed GmbH
Assist Heimpflege-Bedarf GmbH
Astra Tech GmbH
ATMOS MedizinTechnik GmbH & Co. KG
Atos Medical GmbH
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B

B + P Beatmungs-Produkte GmbH
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Bausch & Lomb Surgical GmbH
*Baxter Deutschland GmbH
*Becton Dickinson GmbH
Berlin Heart GmbH
BGS Beta-Gamma-Service GmbH & Co. KG
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*BIOTRONIK GmbH & Co.
*Boston Scientific Medizintechnik GmbH
BSN medical GmbH

C

C. R. Bard GmbH
Cardinal Health Germany GmbH
CeramTec AG
cerboMed GmbH
Chemische Fabrik Kreussler + Co. GmbH
*Coloplast GmbH
Coltène / Whaledent GmbH + Co. KG
ConvaTec (Germany) GmbH
Cook Deutschland GmbH
CORDIS Medizinische Apparate GmbH
Corin Germany GmbH
*Covidien Deutschland GmbH
curasan AG
Cyberonics Europe S. A.

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
Dr. Schmidt Intraocularlinsen GmbH

E

Echosens Deutschland GmbH
*Edwards Lifesciences Germany GmbH
EMKA Verbandstoffe GmbH & Co. KG
ev3 GmbH

F

FOR LIFE Produktions- und Vertriebsgesellschaft für Heil- und Hilfsmittel mbH
Franz Kalff GmbH
*FRESENIUS SE
Fritz Osk. Michallik GmbH & Co. KG
Fuhrmann GmbH

G

*gambro dialysatoren GmbH & Co. KG
*GE Healthcare Accessories & Supplies GmbH
Genzyme GmbH
*GerroMed Pflege- und Medizintechnik GmbH
Gesundheitsteam Bayern 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
*Hollister Incorporated Niederlassung Deutschland
Holthaus Medical GmbH & Co. KG
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I

Illenseer Hospiatlia GmbH
IMI Intelligent Medical Implants GmbH
Impulse Dynamics GmbH
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
Kettenbach GmbH & Co. KG
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KREWI Medical Produkte GmbH
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L

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Licher Medizintechnologie GmbH
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LMA Deutschland GmbH
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M

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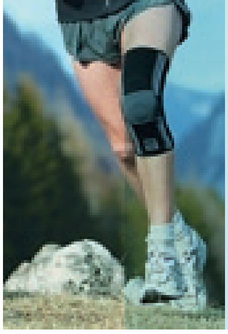
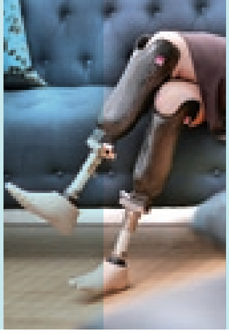
MacoPharma International GmbH
*MagForce Nanotechnologies AG
Maimed Medical GmbH & Co. KG
Maquet Cardiopulmonary AG
Marien Pflege-Beratung GmbH
Mathys Orthopädie GmbH
medac GmbH – Gesellschaft für klinische Spezialpräparate

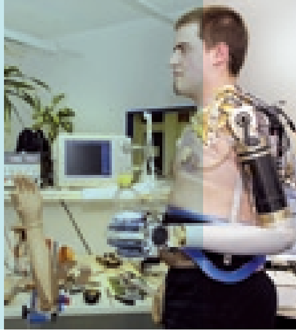




Technical aids for a better quality of life:
bandages, orthotic devices, prostheses and compression hosiery



Modern leg prosthetic



Thought-controlled
arm prosthetic

*medi GmbH & Co KG
Medi-Globe GmbH
Medi1one Medical Großhandels GmbH
Medical Service GmbH
Medilog Handelsgesellschaft mbH
Medizintechnik und Sanitätshaus
Harald Kröger GmbH
MEDOS Medizintechnik AG
*Medtronic GmbH
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MENTOR DEUTSCHLAND GMBH
mepro Medizinische Produktion GmbH
Merete Medical GmbH
Mohage – Mommsen Handelsgesellschaft mbH
Mr. Clean – Gesund Schlafen GmbH
Mundipharma GmbH
*Mölnlycke Health Care GmbH

N
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Nestlé HealthCare Nutrition GmbH
neurotech Bio-Medical Research GmbH
NOBA Verbandmittel Danz GmbH u. Co. KG
noma med Schütze / Schuster GbR
Novo Klinik-Service GmbH

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OptiMed Medizinische Instrumente GmbH
ORIPLAST Gebr. Krayer GmbH
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PlasmaSelect AG
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POLYTECH Health & Aesthetics GmbH
POLYTECH Ophthalmologie GmbH
PubliCare GmbH
*PULSION Medical Systems AG

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*Q-MED GmbH

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Raguse Gesellschaft
für medizinische Produkte mbH
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Rayner Surgical GmbH
rehaVital Gesundheitsservice GmbH
RSR Reha-Service-Ring GmbH
R. Cegla GmbH & Co. KG
Rölke Pharma GmbH

S
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Sangro Medical Services GmbH
Sanicare GmbH
SANIMED GmbH
Sanitop GmbH
Sanitätshaus Aktuell GmbH
SCA Hygiene Products GmbH
*SENGEWALD Klinikprodukte GmbH
Servona GmbH
servoprax GmbH
SFM Süddeutsche Feinmechanik GmbH
Signus Medizintechnik GmbH
SIGVARIS GmbH
Sirtex Medical Europe GmbH
SMB Sanitätshaus Müller Betten GmbH & Co KG
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Smiths Medical Deutschland GmbH
Sonic Innovations GmbH SANOMED
sorbion deutschland GmbH & Co. KG
*Sorin Group Deutschland GmbH
Spring Medical Wilhelm Spring GmbH & Co.
*St. Jude Medical GmbH
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*Stryker GmbH & Co. KG
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Systagenix Wound Management (Germany) GmbH
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