The Medical Technology Companies

BVMed
Enhancing Health.

Annual Report 2003/2004



Patient, Nurse or Doctor; Children or Adults: Medical Devices are indispensable

Contents

Imprint

Published by BVMed – German Medical Technology Association
Reinhardtstraße 29 b, D – 10117 Berlin
Telephone: +49 (0) 30.246 255-0
Telefax: +49 (0) 30.246 255-99
info@bvmed.de
www.bvmed.de
Editor Manfred Beeres, BVMed, Berlin
Translations Cora Berniol, Sandra Pippow
Design buerobeyrow Design und Konzeption, Berlin
Printed by H&P Druck, Berlin
Berlin, March 2004

Cornelia Gröhl,
Chairman of the
board of BVMed

"Innovations: Motor of Our Economy. Hope for Patients."

Dear reader,

the Federal Government has declared the year 2004 as the "year of technology". At the same time Germany has taken an "innovation offensive". In future sectors, research and innovation should be supported to a greater extent. Does this mean that there are good conditions for medical technology - generally one of the most innovative branches? One should think so ..., however, reality looks different.

:: Expenditures for research and development as a proportion of total sales in the medical technology industry have declined from 10 per cent to 7 per cent over the past five years. This is the result of a current BVMed survey.
:: Hardly any research and development in medical technology is being done in Germany anymore. In the US, for example, there is a much more innovation-friendly environment.
:: The trend towards shifting production plants abroad, to Eastern Europe and Asia for example, continues. For the first time in Germany the number of jobs in medical technology has stagnated at 100,000 and is even regressing slightly.
:: Pricing pressure on companies continues to increase, for example due to the DRGs (diagnosis related groups) in the hospital sector or too bureaucratic price-decreasing mechanisms in the technical aids sector. Falling profits in return have a negative effect on investments in research and development.
:: A spiral of continuously falling prices also influences the quality of patient care and the scope of services and education offered by industry.
:: Rigid budgets in some sectors, wrong incentives in the reimbursement system and assessment methods for technology lacking transparency result in a reduced or delayed introduction of innovations in medical technology.

Medical technology companies want to enhance health. We help people to preserve health and live longer and better. We help patients to regain health and mobility and to participate in social and economic life again. A vital society is the prerequisite for a sound economy. We want to reach this goal. However to achieve this, we need a reliable environment and an innovation-friendly atmosphere. Because innovations are the motor of the economy – and patients' hopes focus on medical technological innovations.

2004 is the "year of technology". 2004 must also be the year of shifts in thinking! Innovative medical technologies must be considered an opportunity, an investment in people's health and productive efficiency. For this we need coexistence on a basis of mutual trust and cooperation of all those involved: politicians, health insurance funds, hospital administrators, doctors, nurses and companies.

BVMed is available for this new dialogue as a constructive and open-minded partner: how can we ensure the best possible patient care in our health system in the future? We want to enhance health – together and on a cooperative basis!

Best regards

Cornelia Gröhl
Chairman of the board of BVMed

Medical Devices in Hospitals: From Diagnosis to Surgery and Intensive Care to Postoperative Care, they Save Lives and Preserve Health

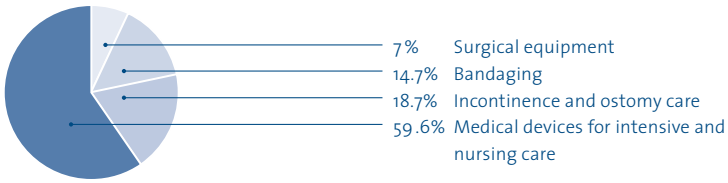
Market and Membership Development

Market development

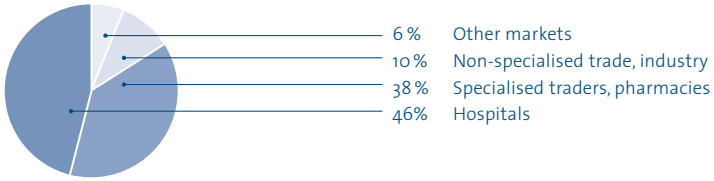
In 2003 an increase in turnover of 3.9 per cent was reported by about 200 industry and trade companies represented by the German Medical Technology Association. Compared to the previous year (plus 6.5 per cent), this is a significant downward trend. The fourth-quarter turnover 2003 rose by 5.1 per cent compared to the same quarter a year ago, which is better than the first half of the year 2003.

The rise in turnover is mainly based on volume growth. The increase in the number of hospital cases is caused by the demographic development and new opportunities in medical technology. Pressure on prices continues, mainly due to budget constraints and the concentration of bulk-buying strength by hospitals. Moreover, costs are rising due to increased sales expenses and rising prices of raw materials. Therefore, the profit situation for companies remains extremely tense. Profit margin accounting of companies increasingly records regressed results. Furthermore, increases in turnover are significantly below the world market development, which is at about 7 per cent.

BVMed sales structure



Sales within subsectors



Development in subsectors

The sector of products for incontinence and ostomy care recorded an above-average 5.9 per cent increase in turnover. The category "single-use devices, intensive care medicine, implants, etc." rose by 4.1 per cent. The development of bandaging materials (1.8 per cent) as well as single-use surgical equipment (2.0 per cent) was much more restrained.

Total expenses for medical devices

According to the Federal Statistical Office Germany, the expenditures on medical technologies in total amounted to 24 billion Euros in 2002. Of this amount, 12 billion Euros account for the outpatient sector (technical aids, other medical supplies), 7 billion Euros for the inpatient sector (material costs in hospitals), and 5 billion Euros for dental prostheses. In 2002 the world market for medical technologies amounted to some 170 billion Euros. Besides the US and Japan, Germany is the world's third-largest market and by far the largest market in Europe for medical devices. In Germany manufacturers of medical devices employ more than 100,000 people.

Sales within subsectors

The sales market structure hardly changed in 2003. Hospitals remained the biggest purchasers of medical devices, as they had been in previous years. They were followed by specialised traders and pharmacies as well as other markets.

Membership development

199 industry and trade companies were members of BVMed (complete list on page 23) at the beginning of 2004. In 2003 eleven companies joined BVMed. At the beginning of 2004 six companies became new members. This is up against 13 withdrawals in 2003, mainly caused by mergers as well as membership adjustments of several companies being united in one group.

Healthcare Policy

Reform of Statutory Health Insurance (SHI): The GMG (law on the modernisation of SHI)

2003 will go down as the "year of reforms" in the history of German healthcare policy. The pressure was inescapable. The reasons have been known for years: structural revenue problems of the SHI caused by the coupling of contributions and wages; high unemployment and a downward economic trend; the rising number of pensioners; the huge progress in medical technology. The chronic financial deficit of the SHI forced politicians to act. Due to the different distribution of power in the Lower House of the German Parliament (ruling majority of the Social Democratic Party and the Greens) and the Upper House (opposition majority of Christian Democratic Union/Christian Social Union and the liberal Free Democratic Party) a common bill was drafted, from which only the liberals pulled out in the end.

The result is the "Act on the Modernisation of Statutory Health Insurance", in short: GMG. Its aim is to relieve the SHI by about 9.8 billion Euros. The reform also aims at reducing the general contribution rate to 13.6 per cent, causing a decrease in non-wage labour costs.

GMG contents

Significant contents of the reform are the exclusion of dental prostheses from the SHI's range of services as of 2005 as well as the self-financing of sick-pay by employees as of 2006. Furthermore, a quarterly practice fee of 10 Euros has been introduced, and co-payment regulations have been redeveloped. As a consequence an additional financial burden of 300 million Euros per year for patients is expected for the supply of technical aids only.

Other central points of the GMG: Integrated Care is to be developed further. Until 2006, up to 1 per cent of the entire reimbursement of both hospitals and health insurance districts will be available for start-up financing. In future a new Joint Federal Committee and the institute for the development of quality and economic efficiency (Institut zur Weiterentwicklung der Qualität und Wirtschaftlichkeit) will take over the tasks of the previous Federal Committees. There is also a new right of application and consultation for institutions representing patients' rights. The medical technology industry will still not be involved in this process. In this connection BVMed demands a procedure-based nomination of experts by those associations concerned.

Next reform: Health bonuses vs. citizen insurance

After the reform is before the reform. The results of the "Rürup Commission" (federal government) and the "Herzog Commission" (opposition party) show the way into the future. Presently, the catchwords "health bonus" vs. "citizen insurance" are the center of discussion. It is obvious that a new direction will have to be taken with the health service. From BVMed's point of view there must be, among other things, more competition between health insurers, more flexibility with regard to financing schemes and more options and responsibility for patients. Thus, BVMed recently suggested a scheme called "delta financing" as an additional financing model for certain areas in order to introduce medical technical innovations more quickly. This model would allow health insurance funds to reimburse the "basic value" of a conventional method or device even if an innovation was used. The "additional value" or benefit of the innovation – referred to as the Delta – would be covered by the patients. So far, this has been prevented by the regulations of the German Social Security Code.

BVMed's healthcare policy activities

Regular health policy discussion evenings with members of the Lower House and decision makers from the health insurance funds', hospitals' and doctors' scene, are the basis of BVMed's extensive schedule in Berlin's political arena. BVMed's summer reception, which was attended by numerous members of all the Lower House's parliamentary parties, is becoming a regular occasion for representatives of associations, politics and decision makers of the health service. BVMed has established itself in the capital as a political heavyweight for the concerns of the medical technology industry.

Typical Medical Technologies in Hospitals: Pacemaker, Intracardiac Navigation System for Use in Cardiac Catheterisation Laboratories, Knee and Hip Implants

DRGs in Hospitals

Introduction of the G-DRG system

The new DRG system in hospitals ("German Diagnostic Related Groups" - G-DRG) has been introduced step by step: At the beginning of the optional year 2003, 288 hospitals started with the G-DRG version 1.0. The number of hospitals that do their accounting according to the DRGs, rose to 900 hospitals by the end of 2003.

The first DRG catalogue 2003 was hardly representative from an economic point of view. Based on 114 hospitals and their cost accounting figures of the first quarter of 2002, the first German relative weights were fixed with statutory orders by the Federal Ministry of Health, after the self-governing bodies had been unable to reach an agreement. Consequently, high-quality procedures in medical technology were underrated. The lack of coding quality and of the universities' participation in the first calculation had falsified the relative weights of high-performance medicine.

Further development of the DRG system in 2004

BVMed is involved in the further development of the G-DRG system within the scope of the self-governing bodies' "proposal procedure". In this procedure, BVMed is called upon to submit proposals for medical technology companies to the Institute for the Reimbursement System in Hospitals (InEK). Last year, this procedure already improved the new DRG catalogue significantly. In total, BVMed made 17 applications with more than 100 proposals regarding OPS codes (operation procedure codes), new DRGs and the financing of additional fees concerning, among other things, implants, radiotherapy as well as modern wound care. A large number of these proposals were implemented in the new G-DRG catalogue 2004.

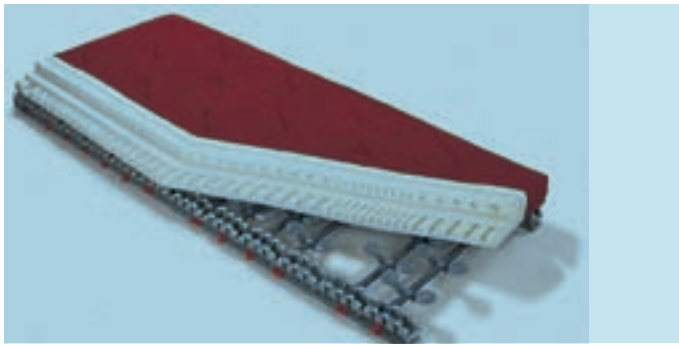
The DRG catalogue 2004, which was again laid down with statutory orders by the Federal Ministry of Health, now contains 824 DRGs. Moreover, every hospital can individually agree on 25 additional fees. This will be the last time that the DRGs as a whole will be "budget-neutral". In 2005 they will gradually be adapted to nationwide base rates. By the publication of the calculation data and project report by InEK, this procedure will become partly transparent. From BVMed's point of view, complete transparency as well as the publication of all hospitals taking part in the calculation is necessary to increase credibility and acceptance of the DRG development process in Germany.

BVMed project: innovations in the G-DRG system

The DRG system is a big challenge for medical technology companies. Economic pressure on hospitals coming from the budgets is passed on to manufacturers. This also affects the willingness of hospitals to include medical technological innovations in medical care under DRG conditions. There is a call for action to ensure that the medical care of patients with innovative medical technologies is not endangered.

For this reason, BVMed, together with the institute for health economy (Institut für Gesundheitsökonomik, Munich), in a project group headed by Prof. Dr. Günter Neubauer, developed a guide for the introduction of innovations in the DRG system. The brochure "Guidelines on the local and decentralized introduction of innovative and novel medical devices" contains practically oriented information for finding typological categories for innovations in medical technology and plans for action. BVMed also carried out numerous workshops on this project.





Typical Technical Aids: Bandages, Orthotics and Technical Aids for Prevention of Pressure Sores

Technical Aids

Pressure on prices endangers quality of medical care

The continuous SHI deficit also leaves its mark in the technical aids market. Manufacturers as well as healthcare providers of technical aids are affected by the economy measures of the health insurance funds. Due to the continuous pressure on prices, the market situation comes to a head. The share of technical aids expenses in the entire SHI expenditures (3.52 per cent) even regresses slightly.

Moreover, healthcare providers often are powerless when confronting health insurance funds. In the past, demanding and pushing through their rights such as the reimbursement of costs at prices agreed upon in contracts or the compliance with administrative procedures was very time-consuming and expensive. The Act on the Modernisation of SHI (GMG) confirms health insurance funds in their previous conduct. In spite of price agreements based on contracts mutually agreed upon, health insurance funds are to have the possibility of limiting reimbursement claims to an average price in the lower third of the price range. This regulation may enable health insurance funds to charge "current prices", varying from day to day, that do not give care providers the planning security required to ensure high-quality and cost-effective patient care. This fortifies the monopoly power of health insurance funds even further, as there still is no regulation on how the determination of average prices must be disclosed. Therefore it is even more important to ensure binding quality levels for medical care with technical aids (products and services), in order to allow for comparisons between different healthcare providers according to equal criteria.

Cooperation BVMed - EUROCOM

Against this background it is even more important to focus the expert knowledge of technical aids associations and to act jointly and in a coordinated way. One step in this direction is the cooperation arranged between BVMed and EUROCOM (European Manufacturers Federation for Compression Therapy and Orthopaedic Devices). According to a survey among member companies, both associations cover all of the 34 product sectors of the medical technical aids register presently existing and are thus available to politicians, health insurance funds and all other participants in the technical aids sector as strong and competent partners.

Tenders in the technical aids sector

With the GMG, the legislator calls on health insurance funds to invite tenders for the conclusion of individual agreements with healthcare providers according to public criteria. This is supposed to apply to all those technical aids that can be purchased directly from the manufacturer without any additional need for advice or adaptation. By now, however, many health insurance funds use various kinds of tendering methods (internet, no public calls for tenders), to also conclude contracts for the supply of technical aids which imply a lot of consultation and service and which in addition are priced much lower than the contract or reference prices dictate. In such bids, the variety of technical aids and the patient's individual need for advice and medical care by qualified and specialised staff can only be depicted insufficiently. The option for patients to choose suitable care providers is negated by tenders. There is a danger of choosing the party to a contract exclusively according to the lowest price of the offer, without taking scope and quality into consideration.

Medical technical aids register (HMV)

In the autumn of 2003 the working group of the National Associations of Statutory Health Insurance Funds published the procedure guide "Structural conditions and procedures in the technical aids and nursing aids sector". The guide was initially presented at a joint conference of the federal association of the IKK health insurance fund (Innungskrankenkasse - IKK), the medical service of the National Associations (Medizinischer Dienst der Spitzenverbände - MDS) and BVMed at the end of September 2003. Since it was a great success, the service event for companies is supposed to take place annually from now on.

Typical Technical Aids for Homecare Therapies: Speech Device for Patient after Laryngectomy and Products for Incontinence and Ostomy Care

Homecare

Homecare is an important part of medical care in the German health service for which all experts assume a positive market development. Essential growth factors are the introduction of the DRGs, the implementation of Integrated Care as well as the demographic development and with it the increasing number of multi-morbidity diseases. The optimistically assessed market development mentioned everywhere must however be put into perspective.

Homecare: Therapeutic care in the home environment

In many cases the press has reported on large development potentials in this sector. However, homecare is often considered to be the same as home nursing. Homecare – as it is defined by industry and trade companies – is not nursing care, but the providing of patients with technical aids/medical devices, pharmaceuticals and medical dressings. Qualified, specialised staff take care of a patient at home and check the success of the treatment prescribed by a doctor. What exactly homecare is as well as its significance for the development of the German health service, its advantages for health insurance funds, hospitals, office-based physicians, outpatient nursing services as well as inpatient rehabilitation and nursing facilities is pointed out in the new BVMed brochure "Homecare" (on the internet at: www.bvmed.de – Publications).

Homecare as a "sector of its own"

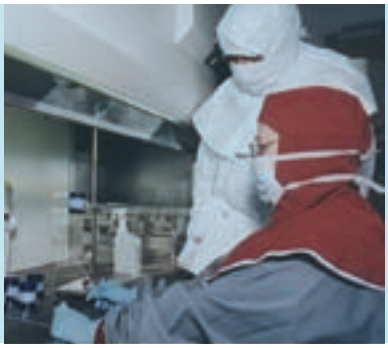
Last year was dominated by the discussion on an increase in efficiency in our health service. The main goal was the stabilisation or decrease of contribution rates in the SHI by the GMG. Legal guidelines however do not aim so much at increasing efficiency in the homecare sector but rather at a price policy of health insurance funds. Aspects like healthcare quality and the comprehensive use of resources taking into consideration the entire treatment costs (outpatient and inpatient) were hardly taken into account. At the same time, companies are confronted with constantly increasing administrative expenses and different implementations of legal guidelines by individual health insurance funds. More and more frequently, courts are asked to provide more clarity and legal certainty. BVMed speaks up for homecare - an entity of products and services - to be recorded in the Social Security Code (SGB V) as a medical care component of its own, and for binding guidelines in quality assurance to be taken into consideration.

Integrated Care structure

Since Integrated Care found its place in the SGB V in the year 2000, it has been put into practice quite slowly. With part-payment regulations regarding the budgets of hospitals and registered medical associations for the start-up financing of Integrated Care, the GMG creates new financial incentives. In the present race for contracts homecare companies take up their position towards their co-operation and contract partners by ensuring that patients are discharged from hospitals smoothly and early, by guaranteeing warranties, by taking over administrative tasks as well as network installations.

Homecare on the European level

Increasing demand for homecare is a typical characteristic of industrial nations. On the European level too everyone is talking about homecare, even if the processes of medical care and their cost allocations are different in each country. Individual developments of this market sector in European member countries offer guidance for the "best practice".


The Production of Medical Devices Must Fulfil the Most Stringent Requirements
(Examples: Production of Implantable Defibrillators, Immunoadsorbers and Instruments for Endoscopy)

Medical Device Legislation

European progress reports

With regard to medical device legislation, 2003 was marked by European "reviews", compiled by the EU Commission and the Council of Europe. The reports referred to both the EC guidelines according to the "New Approach Review" in general and the guideline 93/42/EEC on medical devices ("MDD Review") in particular. A new European legislative procedure for changing drug legislation was introduced. It became known as the "Pharma Review" and is relevant for the future definition of drugs and medical devices.

The reports confirm that the EU's "New Approach Review" has basically proved successful. It is characterised by the fact that manufacturers can place their products on the market at their own risk and in compliance with Essential Requirements harmonised within Europe - with the help of assessment procedures prescribed by law. Depending on the risk level, this is accompanied by external certifying institutions, nominated on a European-wide basis. An outside characteristic of the marketability within the European Economic Area (EEA) is the CE marking.

All reports contained suggestions on the improvement of the system, especially of controlling mechanisms. As a consequence of these improvement proposals, the guideline 2003/12/EC was passed, which leads to an upgrading of breast implants. As a result of this, a time-consuming and expensive examination of the product specifications of breast implants will have to be carried out by an accredited Notified Body. An outline of guidelines with similar contents was also prepared for certain joint implants, which those European manufacturers concerned refuse vigorously. They argue that an additional examination of product specifications would not demonstrably increase patients' safety. From the scientific point of view, the outlined guidelines were insufficiently founded and were only based on political considerations.

National activities

After numerous legislative changes in Germany concerning medical devices in 2002, hardly any such activities were pursued by lawmakers last year. A new publication of the DIMDI Ordinance of June 2003 regulates the online recording of all notification data according to §§ 20, 24, 25 and 30 Medical Devices Act (MPG) in Germany. Furthermore, in July 2003 the national "ordinance for breast implants" came into effect, which is useful for the implementation of the guideline 2003/12/EC (upgrading of breast implants).

Concept for market surveillance

Discussions have continued among the federal states of Germany, which are responsible for the implementation of medical device legislation, on how market surveillance for medical devices can best be carried out. Two federal states, North-Rhine Westphalia and Lower Saxony, take the view that the MPG gave them "no alternative" but to check all assessment steps within the manufacturers companies, which were not checked by the Notified Bodies, "on an appropriate scale". "Appropriate scale" means that tests were done in detail. All other federal states continue to confine themselves to preventive spot checks, unless dangerous market incidents require repressive defence mechanisms.

The majority of the states justify a spot check with a different understanding for the MPG. They also argue that industry as an economic motor must not be overloaded with new regulations which threaten their livelihood during hard economic times and must be given a "chance to survive".

Patient and User Safety Come First! Single-use Catheter in Sterile Solution and Safety Devices for Prevention of Sharps Injuries

Patient and User Safety and Environmental Issues

In focus: Sharps injuries

Infections are a special danger for staff employed in medical institutions. While the number of workplace accidents and occupational diseases generally decreased, this was not the case in so-called sharps injuries. Experts estimate that every year at least 500,000 stab, incision and scratch wounds take place in hospitals. This can lead to infections with hepatitis or AIDS viruses. Apart from medical staff and patients, cleaning and disposal staff are also affected.

At the end of 2003, the prevention of injuries with pointed or sharp objects was therefore rated more highly by the setting up of the "technical rule for the handling of biological working material" (TRBA 250). One claim is: "Sharp, pointed or fragile devices are to be substituted by such suitable devices or techniques that involve no risk or hardly any risk of stab and incision wounds". In October 2003 a BVMed workshop gave representatives of the employers' liability insurance associations, the statutory accident insurance companies and industry the opportunity to discuss measures for reducing sharps injuries by, for example, using safe medical devices.

Re-use of single-use medical devices

If, contrary to the manufacturer's specifications, medical single-use devices are reprocessed and again used on a patient, the manufacturer will not take responsibility for any consequential damage. Instead, according to the Medical Devices Act, the operator and user will have to do so. It is all the more surprising what the GfK HealthCare survey results revealed in 2003. It was carried out on behalf of BVMed and the association for insured people and patients (Vereinigung für Versicherte und Patienten). Among nine medically specialised disciplines, there was no group in which all people asked were aware of their responsibilities. On the other hand, only 13 per cent of approximately 1,000 citizens asked were informed about the re-use of single-use medical devices. Accordingly, the large majority of those asked demanded to be informed of the intended re-use of single-use devices in future, and more than 90 per cent pleaded for the option to reject the re-use of reprocessed devices.

Environmental issues

In 2003 the discussion on the implementation of the packaging ordinance in hospitals was revived by new suppliers turning up. A MedInform event informed about this topic. There is a completely new and comprehensive collection of guidelines, the consequences of which can hardly be anticipated. This plan of reforming the European legislation for chemicals is called REACH guideline, "Registration, Evaluation and Authorisation of Chemicals". In its statement on the EU Commission's first draft, BVMed demands to exclude medical devices from the plan's scope of application. The reason for this is the high safety level of guidelines for medical devices. Especially small and medium-sized companies would be affected by a large amount of work and higher expenses. Experts expect considerable changes in the guidelines, which will not come into effect until 2006. The national implementation of EU guidelines on used electrical equipment and the reduction of dangerous substances in electrical equipment is another significant environmental issue.

Bar Codes

In 2003 BVMed carried out a survey of member companies in order to ascertain the importance of the so-called "auto-identification systems" for medical devices, such as bar code technologies and transponder technologies. The results showed that 63 per cent of companies involved use EAN bar codes and 13 per cent the HIBC bar code. A BVMed team is now creating introductions for the companies, the aim of which is to give "newcomers" to the use of bar codes a start putting them into practice and to prepare the ground for the use of bar codes by mutual agreement. Thus, if possible, efficiency potentials for suppliers and customers in the healthcare market can be implemented in the end.


Events on Innovations: BVMed Press Seminar and Patient Information Day presented by PR Campaign "Aktion Meditech" – including Live Transmission of a Stent Implantation from a Catheterisation Laboratory

Communication / Press

Information on the value and the benefit of medical technologies in the German health service is the focus of BVMed's external communication activities. Information is mainly directed at experts in the public and expert media. However, BVMed increasingly offers information opportunities and new service areas to the public at large or to the "final consumer" of medical devices, the patient. For this purpose for example, an innovation pool was created three years ago at www.bvmed.de, which is one of the services offered by BVMed on the internet to the public at large. Another example is the project "Medical technologies for babies and children", which includes more than 40 different therapies and products.

PR Campaign "Aktion Meditech"

The PR campaign "Aktion Meditech – Living better with medical technology", launched in 2003, is also addressed to the public at large. Involved in the campaign "Aktion Meditech" are doctors and patients, individuals, groups, companies and associations, among them BVMed. The campaign "Aktion Meditech" has made it its business to inform on new treatment methods in medical technology, to encourage those involved in the health service to have discussions, and to ensure that patients affected get a chance to participate in healthcare policy. The common goal is a healthcare policy that deals more with patients' aspects. In order to achieve this, the campaign forges alliances between doctors, patients and patient organisations, health economists, hospitals, industry and other parties involved. Among other things, the activities consist of information events for patients and discussion forums, a quarterly newsletter, media work as well as a website www.aktion-meditech.de with relevant information on every aspect of medical technology for all target groups.

"Health First" & action group "Initiative Vitale Gesellschaft" (vital society)

On the European level, the action group "Health First" has the same goal. Presently, 15 patient and professional organisations as well as numerous Members of the European Parliament, experts and associations, among them BVMed, are members of Health First. The action group focuses on informing the public on innovative medical technologies, in order to also ensure patients' access to medical progress in future. You will find more information on the internet at www.healthfirsteurope.org.

BVMed is also actively involved in the action group "Vitale Gesellschaft" (vital society) at the federal association of German industry (Bundesverband der Deutschen Industrie - BDI). The vision is: excellent health until a ripe old age. The aim is to make Germany a center of excellence for a vital society, so that people live healthier, better and longer lives. Central demands are: research more and more efficiently; quicker availability of innovations for all people; making the healthcare system ready for the future. Find out more at www.vitale-gesellschaft.de.

Media work and internet

BVMed's media work is mirrored in more than 600 newspaper and magazine articles in the expert and economic press by press reports, press conferences, articles and contributions from external authors, joint media projects as well as the fourth BVMed press seminar in the run-up to the Medica 2003. This represents a 20 per cent increase over the previous year. The continuous supply of information is supplemented by weekly newsletters, an up-to-date newsmail service as well as press releases and monthly BVMed reports in English. BVMed's website www.bvmed.de recorded approximately 6 million hits in 2003 (25 per cent more than in the previous year). For member companies the extranet as a central information and communication platform was extended even further.

6th E-Commerce conference

With the sixth of such e-commerce conferences in February 2004 on topics of electronic communication and procurement, BVMed created an "industry get-together" and an information and communication platform for hospitals, manufacturers and service providers.

Medical Devices in the Focus of BVMed Sectoral Interest Groups: Bandages, First-aid Products as well as Technical Aids and Systems for Prevention of Pressure Sores

Reports from BVMed's Expert Committees

With more than 40 focus groups, sectoral interest groups and working groups, BVMed offers its members a platform for constructive dialogue and exchange of views, leading to a unified position on matters of common interest.

Focus groups deal on a continuous basis with topics of general concern to all members, irrespective of their particular products.
Sectoral interest groups consist of members working in a specific market or product area, who desire additional representation of their particular specialist interests.
Working groups are committees set up on a temporary basis to deal with specific subjects, providing expert support to the BVMed board and the management team.

Focus Groups

Healthcare Systems

Legal Affairs

Regulatory and Public Affairs

Environment

Electronic Communication

Focus Groups

Focus group "Healthcare Systems" (AKGS)

AKGS is concerned with matters pertaining the reimbursement of expenses, distribution channels and economic health considerations from the medical technology and trade companies' point of view. In addition the focus group analyses and evaluates legislative procedures and initiatives and prepares position statements for hearings. In 2003 the main areas were the analysis of and statements on the healthcare reform as well as the further development of the DRG system (DRG amendment law and DRG ordinance). Decision makers, such as health insurance management boards, were invited to discuss reform suggestions and points of view on innovative therapy plans for medical technology. This is meant to become a "health insurance forum for medical technology". Moreover, one AKGS team supported the creation of a DRG guideline for the introduction of innovations. Realising the fourth Innovation Congress "Conceptions and models of qualitative and transsectoral patient care with innovative medical technologies" was another focus of work.

Focus group "Legal Affairs" (AKR)

This group co-ordinated the updating and revision of the "WiKo - Wiesbaden commentary on medical device legislation" that was published in October 2003. The legal decisions based on the Medical Devices Act have been commented on and incorporated into the WiKo by AKR and several members of the "Network Medical Device Legislation", associated with AKR. It consists of eight lawyers specialising in medical device legislation. Other high profile topics were the settlement of different legal issues from BVMed's expert committees, European legislative procedures for changing the guideline 2001/83/EC (community code relating to medicinal products for human use - "Pharma Review"), increase of consumer awareness on the significance of CE markings on medical devices, assessment of the new law for device and product safety (GPSG) as well as the participation in the first German Day of Medical Device Legislation 2003.

Focus group "Regulatory and Public Affairs" (AKRP)

With its ten sub-groups, AKRP answers a lot of different queries from industry, trade, authorities and external associations concerning regulatory matters. Main subject areas were questions from the European Commission on the "New Approach Review" and "MDD Review" as well as from national authorities on the change of the Medical Devices Ordinance and Medical Devices Operator Ordinance. In addition, views were exchanged with national and federal authorities, German and European associations and organisations for standardisation. With events and publications member companies were prepared for the introduction of the risk management system as well as the new quality management system for medical devices. Other topics were: Implementation of statutory duty of notification and obligatory registration; market surveillance; necessity of insurance certificate from German insurance companies as a prerequisite for carrying out clinical trials; classification and differentiation issues as well as electronic labelling ("E-Labelling").

Focus group "Environment" (AKU)

AKU had talks with new providers of concepts for packaging disposal in medical institutions and evaluated the importance of their service for the BVMed members. Other main subject areas were the guideline for used electrical equipment and legislation for EU chemicals. Furthermore, AKU commented on specific questions on



substances and materials as well as on corresponding inquiries from authorities regarding for example, medical devices made of natural rubber latex and PVC. At the same time, these questions were also discussed in the working groups "Natural Latex" and "PVC".

Focus group "Electronic Communication" (AKEKOM)

AKEKOM established the sub-group "Bar Codes", which aims at supporting and facilitating the use of bar codes by BVMed member companies. The first measure taken by the group has been the development of introductions for the use of bar codes.

Sectoral interest groups

Sectoral interest group "Bandages" (FBB)

FBB actively cooperates with EUROCOM. Apart from clarification of the value added tax problem, the main interest here is the completion of the product group 23 "Orthotics/splints" of the medical technical aids register. On this issue a meeting with the medical service of health insurance funds (Medizinischer Dienst der Krankenkassen - MDK) and the federal association of the IKK health insurance fund (Innungskrankenkasse - IKK) took place in February 2004.

Sectoral interest group "Blood" (FB Blood)

FB Blood is the contact group for questions on blood bags and devices for apheresis. It continued its cooperation with the Paul-Ehrlich-Institute (PEI). A simplification of the "admission" procedures for blood bags was passed. In correlation with this, the "admission" procedures for devices for apheresis and their corresponding blood bag sets are also to be simplified.

Sectoral interest group "Brachytherapy" (FBBT)

The working group "Interstitial Brachytherapy" (Seed method) of the sectoral interest group FBBT helps to develop and promote this form of therapy in the outpatient as well as inpatient field of application. Seed therapy managed to be adopted into the DRG system in 2004. Procedural proposals for the depiction of intracoronary brachytherapy in the DRG system were submitted

Sectoral interest group "First Aid Materials" (FBEH)

The manufacturers of first aid kits for vehicles and company premises and of medical emergency equipment in FBEH were mainly concerned with the update of first aid materials according to the latest findings in emergency medicine. Further topics were, among other things, the "green dot" ("Der Grüne Punkt" – symbol for recycling) on first aid kits and the expiry date on sterile products. Manufacturers of vehicular first aid kits in the sub-group "Communication" (AGK) continued their press mailings, in which they regularly inform road users on the findings of first aid and the use of vehicular first aid kits.

Sectoral interest group "Ethylene Oxide Sterilisation" (FBEO)

FBEO was founded in 2003 as a forum of companies concerned and as a contact body for authorities and organisations. Its members are either manufacturers of medical devices sterilised with ethylene oxide (EO), or service providers offering EO sterilisation, or companies selling EO sterilisers to hospitals. Main subject areas are relevant legal and administrative rules as well as national and international standardisation.

Sectoral interest group "Medical Technical Aids against Decubitus Ulcers" (FBHD)

FBHD has, in cooperation with the Technical University Berlin, worked on a questionnaire to assist physicians, nursing staff, those bearing the costs as well as those affected in their choice of decubitus products for a particular situation. This selection aid, together with the already existing glossary, are to be united in a user brochure.

Sectoral interest group "Homecare" (FBHC)

FBHC, as a cross-therapy expert committee, deals, among other things, with the development of comprehensive forms of care (Integrated Care, Disease Management

Sectoral interest groups

Bandages

Blood

Brachytherapy

First Aid Materials

Ethylene Oxide Sterilisation

Medical Technical Aids against Decubitus Ulcers

Intraocular Lenses

Cardiovascular Medical Devices

Health Insurance Law for Medical Aids and Therapy Providers

Medical Technology Implants

Modern Wound Care Products

Absorbing Incontinence Care (Manufacturers)

Consultation Overheads, Practice Supplies, Medical Dressings

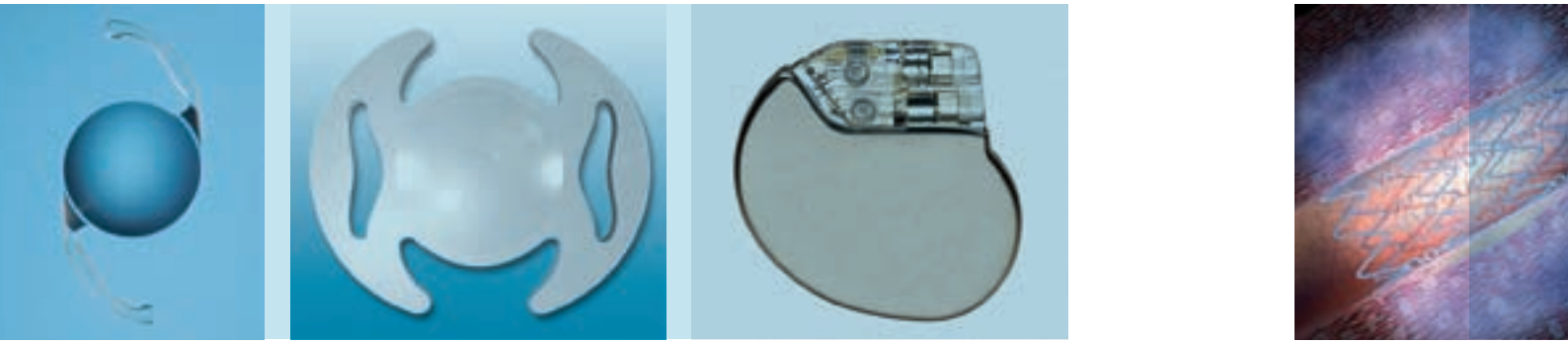
Supply of Sterile Products

Radiation Sterilisation

Ostomy/ Incontinence Care

Therapeutic Apheresis

Tracheostomy/ Laryngectomy



Medical Devices in the Focus of BVMed Sectoral Interest Groups: Intraocular Lenses, Pacemakers, Stents, Intervertebral Disc Implants or Hip Implants

Programmes) and the possibilities of integrating industry and trade companies. With its comment on the GMG draft the group achieved that industry and trade companies will be included in the law when it comes to making medical care contracts. Moreover, FBHC contributed to the BVMed brochure "Homecare", which was published at the beginning of 2004.

Sectoral interest group "Intraocular Lenses" (FBIOL)

FBIOL's most important topic was the analysis of models for the reimbursement of intraocular lenses. In this connection, the question of how high-value care of cataract patients can be maintained in times of limited funds is of immediate importance. In order to achieve this, the group intends to establish initiatives with doctors' associations, involving well-informed patients. Other topics are the safety and quality of intraocular lenses (IOL) and cataract surgery, active involvement in trade fairs and conferences, as well as the redesigning of IOL statistics.

Sectoral interest group "Cardiovascular Medical Devices" (FBKMP)

FBKMP's activities are aimed at securing reimbursement for cardiovascular medical devices in both the in- and outpatient reimbursement procedures. Concerning this, FBKMP compiled suggestions on the appropriate consideration of cardiovascular medical technologies, such as pacemakers, ICDs or drug-eluting stents in the DRG system.

The sub-group "Active Implants" (AGAI) concluded a cooperation agreement with the academy of the German Cardiac Society (Akademie der Deutschen Gesellschaft für Kardiologie) on a training course on the qualitative application of complex pacemaker systems.

Sectoral interest group "Artificial Feeding" (FBKE)

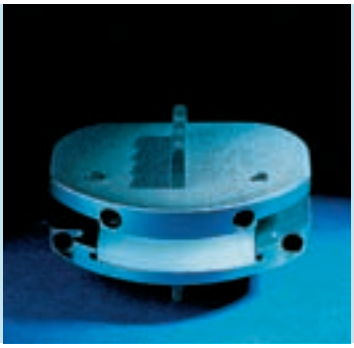
One of the main subjects of FBKE was the value added tax for enteral nutrition therapeutics. Together with the dietetics association, BVMed was able to make a non-objection arrangement for the taxation of drink and tube feeding, based on both the governmental and the federal states' level. Thus, a feasible solution was achieved for the settlement of tax rates in the past. Other topics were the new version of the pharmaceutical guidelines (Arzneimittelrichtlinie – AMR) on the reimbursability of enteral feeding, as well as the establishment of contract terms for agreements on association level concerning enteral feeding therapy (quality standards, reimbursement structures, administrative demands).

Sectoral interest group "Health Insurance Law for Medical Aids and Therapy Providers" (FBLL)

FBLL analysed technical aids regulations of legislation pertaining to the German healthcare reform and developed statements and proposals for draft bills. A special co-payment arrangement for technical aids intended for consumption could be achieved. The lowest contract price as a benefit-in-kind claim was rejected in favour of the determination of an average price of about one third or less in individual contracts, and the health insurance funds' right to information was changed. The clarification of legal issues concerning the range of services that are relevant for technical aids providers were another focus. FBLL's sub-group "Legal Issues" was concerned with complex legal matters, such as the tendering process for health insurance funds and legal guidelines for the awarding of contracts. Moreover, the group worked on a contract model for the conclusion of contracts according to § 127 paragraph 1 of the Social Security Code, Book V.

Sectoral interest group "Medical Technology Implants" (FBMTI)

FBMTI mainly dealt with the assessment of DRGs that are important for endoprosthetics. Together with medical expert institutions, proposals on the adaptation of the DRG catalogue were compiled and submitted to the DRG institute (InEK). Other important subjects were analyses of health policy developments within the implants sector, congress management, PR measures on the "Bone and Joint Decade", the structure of a German endoprostheses register as well as a legal assessment of the topic "assistance in the operating theatre".


Sectoral interest group "Modern Wound Care Products" (FBMW)

The aim of FBMW is to increase the level of knowledge and argumentation for the use of modern wound care therapies both in outpatient and also increasingly in post-inpatient care. Concepts for modern wound care become more and more important, mainly due to shortened hospital stays as a result of the introduction of the DRGs and the increasing significance of chronic wound treatment.

Sectoral interest group "Absorbing Incontinence Care (Manufacturers)" (FBI)

This group is concerned with new reimbursement models and measuring methods. Moreover, together with the FBSI, the group committed itself to achieving another hearing concerning the update of the product group 15 "Incontinence aids" of the technical aids register. It also contributed to the development of BVMed's comprehensive statement on this update.

Sectoral interest group "Consultation Overheads, Practice Supplies, Medical Dressings" (FBSRV)

In several talks with the National Association of Statutory Health Insurance Physicians (KBV) and the National Associations of the Statutory Health Insurance Funds, FBSRV has made clear the position of the manufacturers on the new EBM 2000plus. With its arguments, FBSRV managed to maintain the individual prescription of medical dressings. Furthermore, the amount and the subdivision of the flat rates proposed in chapter 40 of the EBM 2000plus will be checked once again. In connection with the healthcare reform, current main subject areas were the maintenance of co-payment regulations for medical dressings per prescription line as well as the possibility to prescribe medical dressings. In order to clarify the situation for all participants in the market, FBSRV has developed an information card called "how medical aids can be reimbursed and prescribed".

Sectoral interest group "Supply of Sterile Products" (FBSV)

FBSV dealt with issues concerning sterile products and their application. It was supported by specialised sub-groups. Within the sub-group "Supply of Sterile Products" (AGSV) the convergence of European and international standards for sterile product packaging was commented on and actively addressed by an external expert. The sub-group "Returns" (AGR) is a contact group available for all questions concerning the handling of potentially contaminated returned medical devices. The sub-group "Catheters" (AG KATH) is the forum for special issues concerning catheter users and corresponding authorities.

Sectoral interest group "Radiation Sterilisation" (FBS)

FBS is the forum of radiation plant operators and deals, among other things, with the sterilisation of medical devices. The most important subject the group worked on was the standard sequence ISO 11137, which are to be taken over as European EN norms. Furthermore, FBS is concerned with technical issues, the requirements of the radiation protection ordinance as well as the question on how the international representation of the affected companies' concerns can be strengthened.

Sectoral interest group "Ostomy/ Incontinence Care" (FBSI)

This group has committed itself to achieving another hearing concerning the update of the product group 15 "Incontinence Aids" of the technical aids register. A comprehensive statement was developed for the new hearing.

Sectoral interest group "Therapeutic Apheresis" (FBTA)

FBTA's members are providers of technology for extracorporeal blood cleansing. They mainly support an appropriate consideration of their technologies in the hospital DRGs.



Medical Devices in the Focus of BVMed Working Groups: Hydrocolloid Dressings or Artificial Heart Technologies

Working groups

Electrostimulators

Peripheral Vascular Interventions

Re-Use

Material Costs and Outpatient Surgery

Sets

Tissues

PG VAD/ Artificial Heart

Sharps Injuries

Working groups

Working group "Electrostimulators" (PG ESG)

The working group ESG supports the fast development of the product group 9 "Electrostimulators" of the technical aids register. In addition and together with other professional associations, it creates a guideline for the provision with electrostimulators.

Working group "Peripheral Vascular Interventions" (PGPVI)

The newly founded working group PGPVI supports medical technological procedures of interventional catheter therapy (PTA) for the treatment of peripheral occlusive arterial diseases and carotis PTA. The main subject areas in the first year were the appropriate classification in the G-DRG system as well as the creation of a scientific register.

Working group "Re-Use" (PG Re-Use)

The working group Re-Use initiated a comprehensive survey on the problems of re-using medical single-use devices, in which doctors, nursing staff and citizens gave their views on this topic. The group thoroughly examined the "HTA report" for the assessment of reprocessing possibilities in the case of single-use devices, and carried out the fourth MedInform event on this topic. By sending out their "Re-Use News", the working group constantly informed on occurrences and measures, also in other countries.

Sectoral interest group "Tracheostomy/ Laryngectomy" (FBTL)

FBTL has developed an information card on the reimbursability of tracheostomy and laryngectomy products and, moreover, a guideline for the care of tracheostomised and laryngectomised patients as well as quality standards for service providers.

Working group "Material Costs and Outpatient Surgery" (PGSAO)

With suggestions on the appropriate depicting of innovative and established medical technologies, PGSAO addresses the restructuring of contractual arrangements concerning outpatient surgery according to § 115 b of the Social Security Code, Book V.

Working group "Sets" (PGS)

PGS has created an information flyer on the "necessity of uniform rules on the assumption of costs by the SHI for medical care sets in the outpatient sector" as well as a supplementary and explanatory reference book on the subject "Draining incontinence care in the outpatient sector".

Working group "Tissues" (PGT)

PGT addresses the safety of medical devices with regard to the BSE risk as well as the regulation of products containing human tissue. The European guideline 2003/32/EC on TSE relevant medical devices and its implementation into national legislation was the center of interest. PGT developed a statement on the draft of the German ordinance and pleaded for a sensible relation of risk potential and necessary safety measures.

Working group "VAD/Artificial Heart"

The working group VAD/Artificial Heart supports the use of innovative cardiac support systems as well as cardiac replacement technologies. Within the DRG system, reimbursement regulations for these technologies could be established, depicting use and expenses by hospitals more appropriately.

Working group "Sharps Injuries" (AG NSV)

The working group NSV was established in 2003 to draw attention to safety gaps in the use of pointed and sharp objects in healthcare, and to inform on comprehensive possibilities for the safe use of medical devices.




Medical Technologies: Indispensable in all Sectors of Healthcare

Outlook

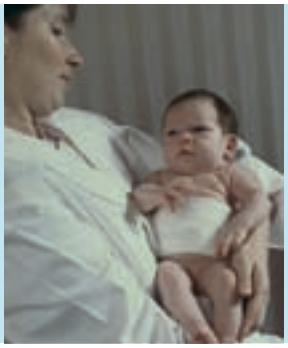
The "wave of innovations" in politics and the "year of technology 2004" give the chance of a shift in thinking in healthcare concerning the assessment of medical technologies. To consider expenditures on medical technologies a pure cost factor is too short-term an approach. They should rather be conceived as an investment in people's health and productive efficiency. Our core messages are:

1. Health is people's most valued possession. Medical technologies are indispensable for people's health and quality of life.
Health is people's greatest good and is essential for the national economy. A healthy and vital society is one requirement for prosperity and economic power. This insight leads to the phrase expressed by European Commissioner for Health David Byrne: "health equals wealth."
Medical technologies are indispensable for people's health and quality of life. They save lives. They help heal. They see to it that millions of patients in Germany regain their vitality and mobility. Medical technologies play an important role in all areas of German healthcare: in prevention, diagnostics, therapy and rehabilitation. They see us through all stages of life and help us recuperate from the most diverse conditions. This is what we understand by "enhancing health".
Medical technologies are a significant economic factor. Medical technology companies provide more than 100,000 jobs in Germany. They invest some 7 per cent of their turnover in research and development, so that new treatment methods can be developed for ill people.

2. Innovative medical technologies must be made available to all patients who require them, without delay. National economy too benefits from faster healing processes and reduced hospital stays.
Innovative medical technologies are an investment in people's health and productive efficiency. Innovations should be better supported, sooner applied, and more strongly appreciated as an opportunity. Modern medical technologies allow people to live longer, healthier and more independently, with less medical complications and reduced rates of disability. These technological advancements reduce the length of hospital and nursing home stays and thereby make our healthcare system more efficient and productive. This constitutes a benefit for the national economy as a whole.
Therefore, innovative medical technologies must be made available to all patients who require them without delay.

3. To allow patients to be treated with innovations sooner, new ways of financing must be found, such as the so-called "Delta Financing Model".
In order to be able to benefit from the tremendous advantages of new medical technologies, a new course must be set in German healthcare. For this reason, BVMed called for "a new health economy" with competitive elements, more planning certainty for companies and an innovation-friendly climate to help take advantage of the market growth potential of healthcare. We must create incentives for optimized and successful treatment. We also require more competition between health insurance funds, more flexible financing models and increased freedom of choice and responsibility for the patients.
To speed up the introduction of medical technology innovations as an additional financing model for certain sectors, BVMed suggests among other things the so-called "Delta Financing Model". This model would allow health insurance funds to reimburse the "basic value" of a conventional method or device even if an innovation was used. The "additional value" or benefit of the innovation – referred to as the Delta – would be covered by patients. However, the implementation of the" Delta Financing Model" requires an appropriate modification of the German Social Security Law.



Medical Devices are Indispensable – not only in Old Age
Even in the Early Stages of Life, Medical Technologies Save Lives, Maintain Health or Improve the Quality of Life

Medical Technologies for Babies and Children

Medical devices and medical technologies are indispensable – not only in old age. They see us through all stages of life and help us recuperate from the most diverse conditions – also and especially in the case of babies and children.
Even in the early stages of life, medical technologies save lives, maintain health and improve quality of life. This starts with prenatal diagnostics which, even before birth, allow for early detection of health defects that can be treated in more and more cases. Modern medical technologies, such as special respirators, save the lives of premature babies that would – only a few years ago – have otherwise died. Medical technologies remain important in the lives of children as they grow up. Whether it is the simple band-aid on wounded skin or the dressing on a scraped knee: children are aware of medical devices early on. BVMed names the following examples:

Ventilatory support system for premature babies: Due to the medical technical progress of recent years, it is now possible to save the lives of premature babies weighing only 500 grams. One of the contributions of medical technology: Special respirators master the particularities of medical care for neonates.

Defibrillators with special electrodes for neonates and children: Sudden cardiac death can happen to anyone. New electrodes can save neonates and children from sudden cardiac death by means of automated external defibrillators. The new electrodes reduce energy to a level suitable for neonates and children up to 8 years of age.

Cardiac pacemakers for children: Cardiac arrhythmia does not only affect adults – neonates and children can suffer from it too. Advances in technology and miniaturisation offer the chance to provide pacemakers even to neonates and children that have cardiac problems. For the treatment of infants, a pacemaker's life-cycle in combination with its reduced volume are of particular significance. The smallest implantable single-chamber pacemaker weighs only 12.8 grams and offers a life-cycle of 8.3 years – in spite of its reduced dimension.

Diabetes pump for children: Diabetic children can use a small, external and waterproof insulin pump with remote control that can be recharged easily. The pump can be worn on a belt like a cellular phone and provides a continuous and correct insulin release.

Enteral feeding pump for children: For children that have to be fed artificially, there are special feeding pumps fitting in custom carry packs, so that the enteral feeding therapy can be continued wherever they are.

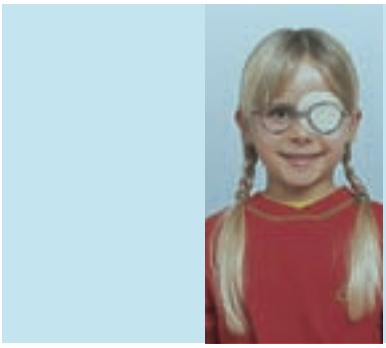
Intraocular lenses for infants: For children suffering from cataracts there are special intraocular lenses. The natural lens is removed and replaced by an artificial plastic lens. The artificial lens is specially adapted to the anatomical conditions of children's eyes.

Cannulae, catheters and catheter securement tape strips for babies and children: In anesthesia, respiratory care and intensive care, special tracheostomy cannulae are used for neonates and children. For the use in pediatrics, medical devices such as catheters, cannulae or tubes are specially developed and manufactured, e. g. special venous indwelling catheters. Peripheral venous indwelling catheters can be protected with special catheter securement tape strips for children. The strips are transparent for crystal-clear control of the puncture site and feature a breathable bacteria barrier.

Special dressings for children: For the use in pediatric care units and operating theatres there is a sterile and waterproof transparent dressing for children, particularly for intravenous applications. For laceration head wounds there are dressings, such as an elastic first-aid head dressing, which are as suitable for children as those for dermal injuries.

More examples at www.bvmed.de – Publications.






New Medical Devices: From Idea to Application

Idea

At the beginning there is always the question: Can I treat a disease with a medical device successfully or improve an existing procedure? Or: A treatment has proved extremely successful in one area – can I apply it in other areas? Such ideas are developed by both doctors and engineers in companies.
Example pacemaker: This principle started with the "simple" stimulation of a heart beating too slowly and was continuously developed, so that nowadays even severe insufficiency of the heart can be treated with a highly intelligent three-chamber pacemaker.

Developmental phase

Technological development itself is subject to maximum safety requirements. The process is accompanied by a risk analysis, which puts the possible risk level of the procedure opposite the corresponding advantage. A comprehensive collection of rules indicates the assessment of these parameters. Numerous laboratory examinations are necessary to ensure the highest possible safety and performance of a medical device before it is first applied on a human being.

Clinical assessment and trial

Whether the new product will fulfil the hopes of developers and doctors will not be known until clinical application. With the development of new technologies unknown territory is frequently entered, so that in most cases innovations are first applied on a patient in strictly controlled clinical studies. Frequently, the study design includes a comparison with the conventional, purely drug therapy. For example, the improvement of the quality of life of patients suffering from cardiac insufficiency by application of CRT therapy, that means with a three-chamber pacemaker, was last proved in an international study. The better the study results are, the more likely it is that new procedures will be adopted into the health insurance funds' range of benefits in the long run.

Testing laboratories

Development, production and final testing of medical devices is carried out on a high level of quality assurance which is supervised by external controlling authorities. A complete and continuously supervised quality management by the manufacturer ensures that the highest demands on material and manageability are met.

CE marking and continuous supervision

According to the Medical Devices Act (MPG) new medical devices may only be marketed when they have a CE marking. It is the "passport" that allows the placing on the market within the European Economic Area. The CE marking may only be attached if high legal safety requirements are met. As a result it represents a high standard of safety, performance and thus, quality of the device. After the device has been launched on the market, the federal states' authorities supervise the safety of medical devices together with the Federal Institute for Pharmaceuticals and Medical Devices (BfArM).

Reimbursement issues

After the medical device has been launched, the next obstacles must be overcome: Will the new device or procedure be reimbursed by health insurance funds? New procedures for the outpatient sector must be adopted into the reimbursement catalogue (EBM) for remuneration according to the doctors' fee scale. Before technical aids are adopted into the medical technical aids register of health insurance funds, they must undergo a long process. New medical technology procedures in the inpatient sector must be profitable, and they are evaluated by federal committees within the scope of technology assessment. In time-consuming processes, procedure codes and DRGs must be introduced. It is a long – a too long? – way from idea to CE marking to application on the patient.




BVMed in Dialogue: Autumn Meeting, Conferences, Medical Technologies on Site, Summer Reception at BVMed in Berlin in 2003

BVMed – We are at Your Service!

Vorstand

Chairman
Cornelia Gröhl
President, Oncology, Ethicon Endo-Surgery (Johnson & Johnson Worldwide)

Deputy Chairmen
Jürgen Bauschke
Managing Director BSN Medical GmbH & Co.KG

Stefan Widensohler
Managing Director MEDIMEX GmbH & Co. KG

Members of the Board
Dr. Gerhard F. Braun
Chairman of the Board, Karl Otto Braun KG

Dieter Buschmann
Director of the Medical Division of PAUL HARTMANN AG

Dr. Dipl.-Ing. Helmut Leuprecht
Chairman of the Board of Lohmann & Rauscher International GmbH & Co. KG

Klaus Moch
Managing Partner of Ludwig Bertram GmbH

Andreas Rudolph
Managing director HSC Home SUPPLY + CARE GmbH & Co. VerwaltungsKG

Joachim M. Schmitt
Director General of BVMed

Head Office

Director General
Joachim M. Schmitt
E-Mail: schmitt@bvmed.de

Assistant: Monika Ridder
E-Mail: ridder@bvmed.de
Tel.: +49 (0) 30 246 255-11

Legal Issues Dpt.
Rainer Hill
Deputy Director General
E-Mail: hill@bvmed.de

Secretary:
Andrea Schlauß
E-Mail: schlauss@bvmed.de
Tel.: +49 (0) 30 246 255-22

Expert on Consumer Affairs/ Medical Technology Dpt.
Elke Vogt
E-Mail: vogt@bvmed.de
Tel.: +49 (0) 30 246 255-17

Secretary:
Antje Kuschel
E-Mail: kuschel@bvmed.de
Tel.: +49 (0) 30 246 255-15

Communications/Press Dpt.
Manfred Beeres M.A.
E-Mail: beeres@bvmed.de
Tel.: +49 (0) 30 246 255-20

Secretary/Assistant:
Sandra Pippow
E-Mail: pippow@bvmed.de
Tel.: +49 (0) 30 246 255-19

Healthcare System Dpt.
Olaf Winkler
E-Mail: winkler@bvmed.de
Tel.: +49 (0) 30 246 255-26

Secretary:
Ute Lieck
E-Mail: lieck@bvmed.de
Tel.: +49 (0) 30 246 255-24

Homecare Dpt.
Oda Hagemeier
E-Mail: hagemeier@bvmed.de
Tel.: +49 (0) 30 246 255-13

Sekretary:
Stefanie Brunz
E-Mail: brunz@bvmed.de
Tel.: +49 (0) 30 246 255-16

Health Insurance Dpt.
Daniela Piossek
E-Mail: piossek@bvmed.de
Tel.: +49 (0) 30 246 255-25

Secretary:
Ute Lieck
E-Mail: lieck@bvmed.de
Tel.: +49 (0) 30 246 255-24

Administration
Marion Guttmann
E-Mail: guttmann@bvmed.de
Tel.: +49 (0) 30 246 255-12

BVMed – Our Services for You

BVMed represents about 200 industry and trade companies. It comprises the entire sector of medical dressings, technical aids such as ostomy and incontinence products or bandages, plastic disposable items such as syringes, catheters and cannulae as well as the implant sector of intraocular lenses, hip, knee, shoulder and spinal implants, heart valves and defibrillators and even artificial hearts. BVMed also represents homecare services and biotechnology procedures, such as tissue engineering.

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, it offers its members a platform for a constructive dialogue and exchange of views. BVMed represents the concerns of its member companies towards policy makers and the general public. This is achieved not only by means of information and public relations work, but also by participation in the compilation of laws, guidelines and standards. BVMed's services can be sub-divided into four sectors:

Organisation

BVMed carries out its task of the joint formation of opinion in more than 40 committees covering specific subjects. You will find more information on this subject in this brochure starting at page 12. In the meantime, a current overview of BVMed's expert committees is available on the internet at: www.bvmed.de – About BVMed.

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 Technical Aids Advertising Act, standardisation plans, or ordinances.

Information

BVMed's multi-faceted information service is evident in both its internal and external communications. Here are some examples:

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

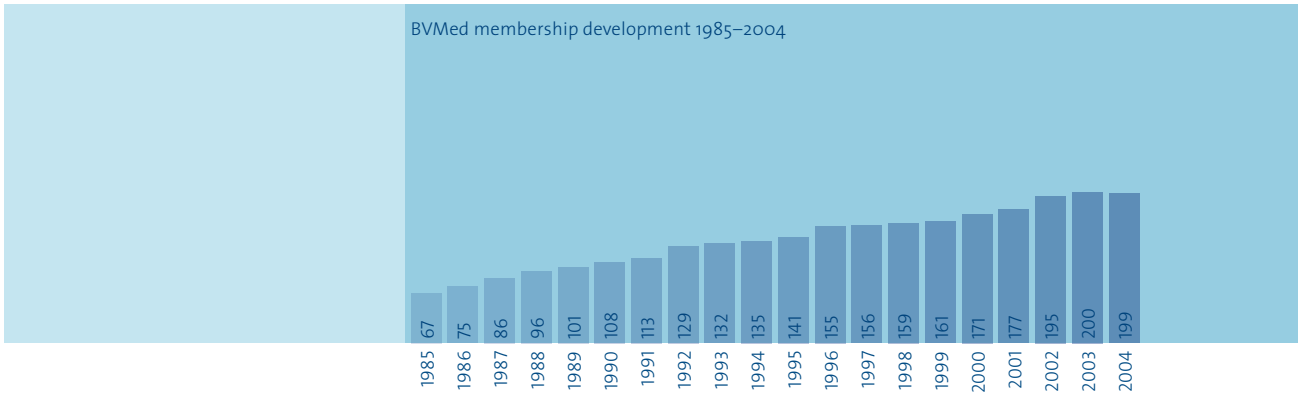
:: Internet presentation www.bvmed.de
:: Broschures
:: Information cards
:: BVMed special conferences
:: MedInform conferences
:: Training seminars (Medical device consultants, seminars on Statutory Health Insurance)
:: Press releases and conferences
:: Press seminar

Representation

BVMed represents the interests of the medical technology branch. Important aspects are among others:

:: Political marketing
:: Individual political discussions
:: Care and support of networks
:: Parliamentary evenings
:: Background discussions
:: Participation in parliamentary hearings as well as
:: Representations in committees, boards of trustees, commissions etc.

How can your company become a member of BVMed? The conditions for membership of BVMed are stated in § 3 of the BVMed statutes, which you can find on the internet at www.bvmed.de (About BVMed) or receive from BVMed on request. Applications for membership must be submitted in a letter to the Director General of BVMed. Please contact us. We will be pleased to help you!



as on 1 April 2004: 199 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
Abena Hygiene GmbH
ABIOMED BV
ACRIMED Pharmazeutische und medizintechnische Gesellschaft mbH
ACRITEC Gesellschaft für ophthalmologische Produkte mbH
ADL Anti Dekubitus Lagerungssysteme GmbH
* AESCULAP AG & CO. KG
* Affina Immuntechnik GmbH
AirMed Prophylaxe + Therapie Systeme GmbH
AirSystems Medizinische Produkte GmbH
* ALCON PHARMA GMBH
ALPHANORM Medizintechnik GmbH
AMEFA Großhandelsgesellschaft mbH für Medizin-Technik
American Medical Systems Deutschland GmbH
AMO (Advanced Medical Optics) Germany GmbH
AMOENA GmbH & Co. KG Medizin-Orthopädie-Technik
Andreas Fahl Medizintechnik-Vertrieb GmbH
Ansell GmbH
ARROW Deutschland GmbH
Assist Heimpflege-Bedarf GmbH
Astra Tech GmbH
Atos Medical GmbH
AURELIA Medical Handel GmbH

B

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

C

C.R. Bard GmbH
* Cardinal Health Germany 206 GmbH
CareTex Medizinische Textilien GmbH
* Centerpulse Orthopedics
* CeramTec AG Geschäftsbereich Medizintechnik
Chemische Fabrik Kreussler + Co. GmbH
Clinico Medical Production GmbH
* Coloplast GmbH
Coltène/Whaledent GmbH + Co. KG
ConvaTec Vertriebs-GmbH
* CORDIS Medizinische Apparate GmbH
CORNEAL GmbH
curasan AG
Cyberonics – Devices for Epilepsy

D

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

E

* Edwards Lifesciences Germany GmbH
Ela Medical GmbH
EMKA Verbandstoffe GmbH & Co. KG
Ethicon GmbH

D

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

G

gambro dialysatoren GmbH & Co. KG
Gamma-Service Produktbestrahlung GmbH
GANZONI GmbH
GARANTOL Products Detia Freyberg GmbH
Genzyme GmbH
* GerroMed Pflege- und Medizintechnik GmbH
GUIDANT GmbH & Co. Medizintechnik KG

H

HAEMONETICS GmbH
Hakle-Kimberly Deutschland GmbH
HANS HEPP GMBH & CO. KG
HEIMOMED Heinze GmbH & Co. KG
* Hill-Rom GmbH
HMT Medizintechnik GmbH
* Hollister Incorporated Niederlassung Deutschland
* Holthaus Medical GmbH & Co. KG
HOMANN - MEDICAL GmbH u. Co. KG
Home Therapie Management GmbH – HTMa
HSC Home SUPPLY + CARE GmbH & Co. Verwaltungs KG
HTMa – Home Therapie Management GmbH
Hudson RCI (Deutschland) GmbH
HumanOptics Deutschland GmbH & Co. KG

I

IBA S&I GmbH
IIP-Technologies GmbH
Impella Cardiotechnik AG
INNOTHERA GmbH
INTRAPLANT medizinische Geräte Vertriebs-GmbH
INVATECH Gesellschaft für fortschrittliche Medizintechnik mbH & Co. KG
Isotron Deutschland GmbH

J

JOBST GMBH Medical Stockings
Jostra AG

K

Karl Beese (GmbH & Co.)
Karl Otto Braun KG
KCI Therapiegeräte GmbH
KEIMED GmbH (HSC)
Kettenbach GmbH & Co. KG
KLUGE medical Gesellschaft für Hygiene- und Medicalprodukte mbH
KRAUTH medical KG (GmbH & Co.)
Kyphon Deutschland GmbH

L

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

M

MacoPharma International GmbH
MainoPharm Pharmazeutische Fabrik GmbH




Living Longer, Healthier and Better: Medical Technologies are Indispensable in all Sectors of Healthcare

MAPA GmbH Gummi- und Plastikwerke
Mathys Orthopädie GmbH
Mathys Osteosynthese GmbH
Medex Medical GmbH & Co. KG
medi Bayreuth Weihermüller & Voigtmann GmbH & Co. KG
* Medi-Globe GmbH
Medical Service Vertriebs-GmbH
Medilog Handelsgesellschaft mbH
MEDTHODIC Bernd A. Harren KG
* Medtronic GmbH
megro GmbH & Co. KG
MENTOR DEUTSCHLAND GMBH
mepro Medizinische Produktion GmbH
Mölnlycke Health Care GmbH
Mundipharma GmbH

N
n:aip Holding GmbH (Netzwerk ambulante Infusions- und Palliativtherapie)
Nestlé Clinical Nutrition GmbH
* neurotech Bio-Medical Research GmbH
NOBA Verbandmittel Danz GmbH u. Co. KG
noma med GbR
Novartis Nutrition GmbH
Novoste GmbH

O
Oncura
ORIPLAST Gebr. Krayer GmbH
OSSACUR AG
Otsuka Pharma GmbH
Otto Bock HealthCare GmbH, Betrieb Maintal

P
P.J. Dahlhausen & Co. GmbH
Pajunk Medical Produkte GmbH
Pall GmbH Medical
PAPER-PAK GERMANY GmbH
PARAM Großhandelsgesellschaft mbH
* PAUL HARTMANN AG
Peter Brehm GmbH Chirurgie-Mechanik
pfm Produkte für die Medizin Aktiengesellschaft
Pfrimmer Nutricia GmbH
Phadimed GmbH & Co.KG
Pharmacia GmbH
PlasmaSelect AG
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
* REGENT MEDICAL eine Division der London International GmbH
rehaVital Gesundheitsservice GmbH
Rentex Vertriebs GmbH & Co. KG
* Ruth Cegla GmbH & Co. KG

S
SANDER Chemisch-Pharmazeutische Fabrik GmbH
Sangro Medical Services GmbH
Sanicare GmbH
Sanitätshaus Aktuell GmbH
SCA Hygiene Products GmbH
SENGEWALD Klinikprodukte GmbH & Co. KG
servoprax GmbH
* Servox AG
SFM Süddeutsche Feinmechanik GmbH
Smith & Nephew GmbH
* Smiths Medical Deutschland GmbH
Spring Medical Wilhelm Spring GmbH & Co.
* St. Jude Medical GmbH
Steritex KG Schneeweiss 1882 GmbH + Co.
Stryker Howmedica GmbH
Stöckert Instrumente GmbH
* SÖHNGEN - W. Söhngen GmbH

T
TECHNOMED Gesellschaft für med. und med.-techn. Systeme mbH
TEMPUR Deutschland GmbH
TERAKLIN AG
TERUMO (DEUTSCHLAND) GmbH
The ROHO Group - ROHO International, Inc.
* Thomas Hilfen für Behinderte GmbH & Co. Medico KG
* THUASNE DEUTSCHLAND GmbH & Co. KG
Tornier GmbH
TRACOE medical GmbH
Tutogen Medical GmbH
* Tyco Healthcare Deutschland GmbH

U
UDO HEISIG GMBH
URGO GmbH
URSAPHARM Arzneimittel GmbH & Co. KG

V
Vereinigte Papierwarenfabriken GmbH
* Vitatron GmbH
VYGON GmbH & Co. KG

W
W.L. Gore & Associates GmbH
WERO-medical Werner Michallik GmbH & Co. KG
Wilh. Jul. Teufel GmbH & Co. KG
Willy RÜSCH GmbH

Z
* Zimmer Chirurgie GmbH

*Available pictures: We would like to thank the companies marked with an asterisk for the picture material they have provided. More product and usage pictures are located on the internet at www.bvmed.de – Pictures.

You can request further information from:
Bundesverband Medizintechnologie e.V.
Reinhardtstr. 29 b
D - 10117 Berlin
Tel.: (030) 246 255-0
Fax: (030) 246 255-99
E-Mail: info@bvmed.de

And on BVMed's website at **www.bvmed.de** you will find among other things:

:: Publication list with info cards, studies etc.
:: Conference overview
:: Press releases
:: Innovation pool
:: Case study pool
:: Pictures
:: Links
:: Glossary and Dictionary

and up-to-date news on the entire German health service.

BVMed – German Medical
Technology Association
Reinhardtstraße 29 b
D - 10117 Berlin
Tel. +49 (0) 30 246 255 - 0
Fax +49 (0) 30 246 255 - 99
info@bvmed.de
www.bvmed.de