

The Medical Technology Companies

∴ ∴ ∴ ∴ **BVMed**  
*Enhancing Health.*

Annual Report 2004/05





Use of Medical Devices in Hospitals



And for First Aid: Emergency Kit for Tracheotomy and First-Aid Bag

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### Imprint

**Published by** BVMed – German Medical Technology Association  
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**Printed by** H&P Druck, Berlin  
Berlin, March 2005



**Anton J Schmidt**  
Chairman of the board of BVMed

## Introduction

# New Culture of Dialogue for a Future-Oriented Health Economy

2004 was the first year after the German healthcare reform, the so-called “Statutory Health Insurance (SHI) Modernization Act”. The reform led to substantial uncertainties among both doctors and patients. It also had a negative impact on the medical technology sector, one of the most innovative and promising branches there is.

The federal government had furthermore declared 2004 the “Year of Technology” in order to contribute to a stronger appreciation of innovative technologies. When it comes to medical technologies, this should not pose a challenge, as the year 2004 once more yielded great breakthroughs in the detection and treatment of diseases. Modern medicine is constantly developing more efficient methods of fighting all kinds of diseases, of alleviating pain and disability. Many of these issues and innovations will be described in more detail in this Annual Report.

Naturally, a rising number of people would like to take advantage of these new methods. They want to be able to choose new, more innovative diagnosis and treatment methods. Unfortunately, this is becoming increasingly difficult, which is, above all, due to the strained financial situation of the SHI. Thus, our society is facing the challenge of establishing what kind of medical services will in the future be covered by the solidary system. This must be the landmark for any new system, be it in the shape of “health premiums” or a “citizen insurance”, which are the two concepts currently discussed at the political level.

At the same time, we need further approaches for solving the structural and quality problems currently existing. In the long term only a fundamental reorganization of the healthcare system with increased competition and market orientation can guarantee affordable, high-quality healthcare. This would presuppose more freedom of choice for the insured as well as an increased individual responsibility of patients for their own health. Thus, it is a crucial task for all participants in the health service to encourage and support people in obtaining health education and health competence.

Germany’s medical technology sector ranks among the best worldwide and with its undisputed growth potential would have the best basic conditions in a future-oriented health economy. One imperative prerequisite for a creative development of this health economy is an intensive exchange of ideas between the political departments of health, economy and research.

Any opportunities for both the sector and for Germany can only be exploited in a joint effort – also and especially for the benefit of the patients. The medical technology companies are available for this dialogue as a constructive and open-minded partner.

Best regards

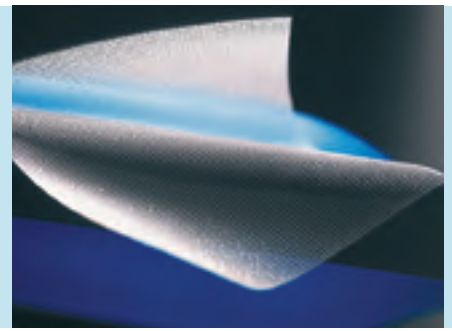
**Anton J Schmidt**  
Chairman of the board of BVMed



Support and Relief Bandaging



Adhesive Foam Heel Dressing



Lipidocolloid Dressing

## Market and Membership Development

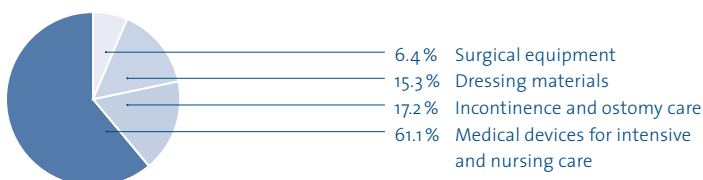
### Market Development

In 2004, an increase in turnover of 1.5 per cent was reported by about 200 industry and trade companies represented by BVMed. Compared to the previous year, this is a downward trend. In 2003, turnover had increased by 3.9 per cent, in 2002 even by 6.5 per cent over the year before. Thus, increases in turnover are below the world market development, which is at about 7 per cent. A representative survey among BVMed's member companies in the fall of 2004 reached a reserved, yet optimistic conclusion for 2005. Some 40 per cent of the companies expect an improvement both in the profit situation and in employment figures over the previous year. 30 per cent see no significant changes.

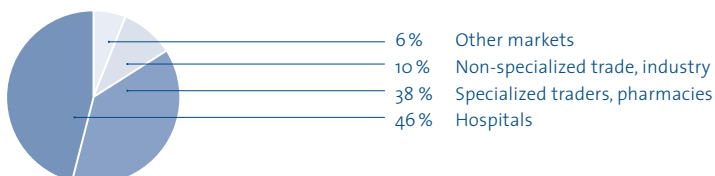
### Development in Subsectors

Especially the sector of medical technical aids suffered from a significant drop in turnover compared to the previous year. Incontinence aids and ostomy care alone reported a decrease in turnover of 2.2 per cent. Due to the rising number of cases and demographic developments, there had still been an increase of 5.9 per cent in 2003. The considerable decrease in 2004 can be attributed to the restrictive measures of the health-care reform, particularly in the technical aids sector. Developments in further subsectors: The category "single-use surgical equipment" decreased by 6 per cent.

BVMed Sales Structure



Sales within Subsectors



Turnover developed slightly positive in the following areas: "single-use devices, intensive care medicine, nursing items" with an increase of 3 per cent, and "dressing materials" with an increase of 3.1 per cent. This rise in turnover, however, is mainly based on volume growth.

### Total Expenditures on Medical Devices

Expenditures on medical devices amount to some 19 billion Euros. Of this amount, 12 billion Euros account for the outpatient sector (technical aids, other medical supplies) and 7 billion Euros for the inpatient sector (material costs in hospitals). The manufacturers of medical devices in Germany employ approximately 108,000 people. The world market for medical technologies amounted to some 184 billion Euros in 2003. The European market, estimated at 55 billion Euros, is the second biggest market in the world, following the United States at 79 billion Euros. Besides the USA and Japan, Germany is the third biggest market worldwide and by far the largest market in Europe. It is about twice as large as the French and three times as large as the Italian and British market.

### Sales within Subsectors

The sales market structure hardly changed in 2004. As in previous years, hospitals remained the major purchasers of medical devices, followed by specialized traders and pharmacies as well as other markets.

### Membership Development

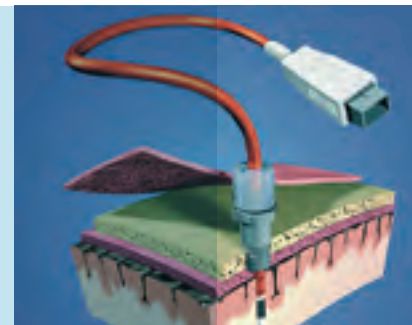
Presently (in March 2005) BVMed represents 200 industry and trade companies. Please find a complete list of BVMed's members on pages 22/23. In 2004, 15 companies joined BVMed. At the beginning of 2005, four further companies became members. This is up against 10 withdrawals in 2004, which mainly resulted from mergers and consolidations.



Single-Use Catheter for Intermittent Catheterization (ISK)



Safety Catheter



Insertion of ICP Catheter through a Bolt

## Healthcare Policy

### Healthcare Reform / GMG

The year 2004, following the SHI Modernization Act's coming into effect, temporarily relieved statutory health insurance funds of some of their financial burden. In the third quarter of 2004, sickness funds reported a surplus of some 2.6 billion Euros. The federal government's objective of decreasing SHI contribution rates to an average 13.6 per cent by way of this reform failed. The surplus realized by the sickness funds was mostly spent on the reduction of their accumulated financial deficits, which amounted to some 8 billion Euros in total.

The positive development of the SHI fund's financial situation is due firstly to increased co-payments of patients, e.g. the practice fee, and secondly to restrictions in the provision of services, which mainly affect the expenditure for pharmaceuticals. Compared to the year before, up to 2.4 billion Euros less were spent on drugs, owing to the exclusion of non-prescription medications from reimbursement as well as to the advanced discount regulation for drugs.

### Medical Technical Aids and Dressing Materials

Medical devices such as technical aids or dressing materials are likewise affected by the reform. Patients are required to make co-payments of at least 5 Euros and a maximum of 10 Euros per item or service. Owing to BVMed's involvement and supply of comprehensive data, the financial burden of these particular patient groups could be organized at a more socially acceptable level with the introduction of a new regulation for the chronically ill (co-payments will not exceed 1 % of their annual gross income) and an indication-oriented regulation for items intended for single use.

The reduced expenditure of 533 million Euros in the medtech aids sector can primarily be attributed to the restriction of SHI coverage for visual aids. The weak development of the SHI funds' contribution-based income, which is marked by continuously high unemployment and a modest wage growth, continues to be an alarming factor. Thus, the financial situation of the sickness funds will remain strained.

### Structural Measures within the GMG

A substantial influence on the design of future medical care will be the newly established Institute for Quality and Cost-Effectiveness in the Healthcare System (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen – IQWiG). One of the institute's tasks is the evaluation of diagnosis and treatment methods involving medical technologies. It is assigned its tasks by the Federal Joint Committee (Gemeinsamer Bundesausschuss – G-BA) or directly by the Federal Ministry of Health. In the Joint Federal Committee, all sectors of healthcare have been merged (inpatient and outpatient care, disease management). A joint procedural order is yet to be established.

The most significant changes for the quality of healthcare begin to emerge with the new provisions for integrated care. This instrument is intended to break through the strict separation of healthcare sectors. By allocating 1 % of physicians' fees or hospital budgets, respectively, to integrated care, the SHI Modernization Act provides an initial financing pool of an annual 680 million Euros for the advancement of this tool.

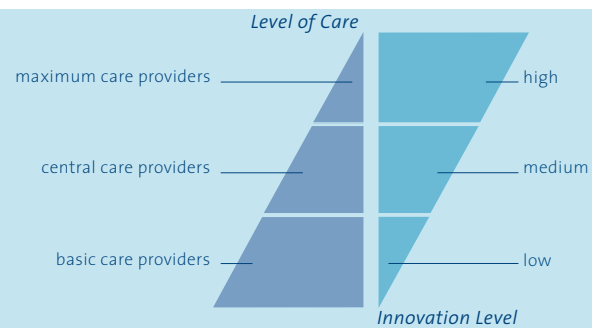
In individual contracts between sickness funds and care providers both horizontal and vertical concepts of medical care can be agreed upon. By December 2004, 239 integrated care contracts had been registered and 89 medical treatment centers had been admitted.

### BVMed's Activities in Healthcare Policy

In order to solve implementational problems of the GMG, BVMed reinforced its numerous contacts to the top and expert levels of the Federal Ministry of Health. In parliamentary breakfasts and dinner talks with parliamentary members of the Lower House's health committee, the concerns of medical technology could be discussed. Furthermore, BVMed intensified its contacts to the federal states ("Länder"), which have a significant interest in the advancement of innovative medical technologies. Another focal point of BVMed's health political activities was the increased cooperation with decision makers in the healthcare system, e.g. representatives of the national SHI associations, doctors or hospitals.



New Diagnostic Solutions: Capsule Endoscopy for the Detection of Diseases in the Small Intestine and Minimally Invasive Breast Biopsy



Innovation Ratio of Hospitals according to their Levels of Care

## DRGs in the Hospital Sector

### 2004: The Year of Mandatory DRG Introduction

2004 was the last budget-neutral year for German acute care hospitals in this new age of DRGs (Diagnosis Related Groups). The German flat-rate reimbursement catalogue (G-DRGs) got hospitals moving. By the end of 2004, 86 per cent of the altogether 1,836 hospitals affected had changed over to the DRG system. This change in hospital reimbursement also alters the structures of the German hospital landscape. Part of the inadequately funded municipal facilities are privatized by their operating institutions or sold to private operators. This does not even stop at maximum care providers such as university hospitals. The financial pressure on hospitals is passed on to the medical technology companies. Procurement of medical devices is standardized and streamlined by purchasing networks.

Under the pressure of another substitutive execution by the Federal Ministry of Health, the self-administration partners of sickness fund and hospital associations for the first time agreed on the DRG catalogue for the coming year as well as on the new rules of accounting. This catalogue is a lot more complex than the previous one. It comprises 878 DRGs and 71 supplementary payments. Supplementary payments also include “emerging” medical technologies, which could not be calculated before.

### Expert Report on the Impact on Innovations

If hospital-individual base rates are adjusted to a uniform national base rate, hospitals with a high hospital-specific base rate run the risk of losing out. This would particularly affect maximum care providers such as university hospitals, which for the most part use innovative, high-value medical technologies (see illustration).

An expert report on the impact of the convergence phase on the innovation potential of hospitals was commissioned from the institute for health economy, headed by Professor Dr Günter Neubauer. The report recommended a differentiation of hospitals according to their levels of care and an extension of the convergence phase until the base rates are adequately adjusted. Parts of this recommendation, such as the

extension of the convergence phase, have found entry into the DRG amendment law. With the report's content, BVMed provided a crucial impulse for the further legal development of this “learning system”.

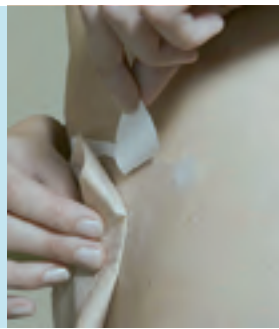
### Second DRG Amendment Law

Before the DRG system can become effective as a pricing system, an appropriate and fair reflection of medical technologies with high material costs is called for. Therefore, the convergence phase had to be adjusted and modified respectively. In a first draft of the 2nd DRG Amendment Law (2. Fallpauschalenänderungsgesetz – 2. FPÄndG) by the Federal Ministry of Health, an extension of the convergence phase by one year and a more moderate level of entry were proposed. From the perspective of the “Länder”, which were required to approve the draft, this proposal did not take matters far enough. They demanded an extended convergence phase of 5 years and the introduction of a capping limit for budget losses. They particularly feared for university medicine and its financial provision.

In order to achieve suggestions for improvement for the adoption of medical technologies, BVMed initiated numerous talks at the political and administrative level. The option of agreeing to prospective excess volumes for emerging medical technologies and an appropriate and fair compensation mechanism for service volumes that are below or above predictions for high-quality medical technologies with proportionately high material costs are of the utmost importance during the convergence phase. In addition, a timely incorporation of innovative medical technologies into the DRG system must be guaranteed. By means of hearings and statements and with the support of the international medical technology associations AdvaMed and EUCOMED, the main part of these suggestions could be brought to bear in the revised legal regulations. For medical technologies with high material costs additional payments reflecting the true technology costs can be provided. Flexibility of the innovation clause will be improved. The convergence phase is extended by two years and the adaptation level will become less steep. In addition, budget redistribution is restricted until 2009 by the introduction of a capping limit.



Ostomy Pouch



Skin Protection Adhesive Barrier for Ostomy Patients



Production of Tracheostomy Tubes



Speech Valve

## Technical Aids

### Impact of the GMG

The SHI Modernization Act (GKV-Modernisierungsgesetz – GMG) had a particularly dramatic impact on the medical technical aids industry. The GMG's taking effect on 1st January 2004 resulted in a multitude of grave changes for the medtech aids sector. In the first three quarters of 2004, these interventions in the technical aids market enforced by legislature led to a drastic decrease of medical technical aids expenditure by 13.7 per cent. The share of technical aids in the SHI's total expenditure within this period of time amounted to only 3.18 per cent – compared to 3.58 per cent in the same period of 2003.

After one year of practical experience with the GMG, the technical aids sector is on the road to radical change. Meanwhile, co-payments, additional payments, nationwide reference prices, changes in reimbursement and the resulting difficulties have left their mark on patients' and care providers' everyday lives. Some of the most significant problems in implementing the legal requirements are due to vague phrasing and the sickness funds' ensuing varied legal interpretations of the law. This has led to great insecurities among all participants in the medical technical aids market.

### Low-Price Policy raises Question of Quality

The GMG caused extreme economic cuts in the technical aids sector. Sickness funds, for instance, revoked existing contracts. Furthermore, an increasing number of care providers had to file for insolvency. This is an unmistakable sign that many care providers will reach their minimum subsistence level before long. But manufacturers were not spared the GMG's repercussions either. Due to the increased pressure on sales and prices, they were forced to accept drops in turnover of up to 40 per cent.

This initiated low-price policy harbors the risk of causing a decline in quality in the medium term. It is feared that care providers will not be able to maintain their service in the present quality. Manufacturers are increasingly forced to relocate their production facilities to low-wage countries and/or reduce the high quality of their products to a sickness fund standard quality.

### Federal Reference Prices

On 1 January 2005, federal reference prices for various product groups of the medical technical aids register came into effect. For the moment, only the following product categories are concerned: arch supports, technical aids for compression therapy, visual and hearing aids, as well as absorbing incontinence aids. In the long term, it is planned to stipulate reference prices for 70 per cent of all medical technical aids.

In total, 253 reference prices were determined. During the hearing phase, which BVMed actively participated in, 35 per cent of the prices were increased, 64 per cent remained at the same level. One reference price was decreased. However, in several areas reference prices still fall far short of the requirements. Thus, in ostomy care, a market-share weighted drop of some 13 per cent in the price level has occurred. In individual cases even the lowest "Länder"-wide reference price was severely undercut, as is the case with base plates (technical aid registration number 29.26.05). The partial increase of reference prices during the hearing phase can nonetheless be considered a first success. Next to the qualified in-depth statements of BVMed's sectoral interest groups, the continuous cooperation with the national associations of statutory health insurance funds as well as the joint public relations work with affected care providers and patient groups were instrumental in achieving this.

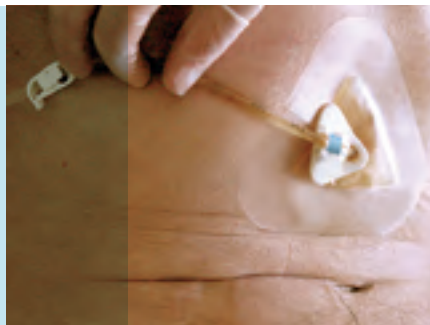
The fact that the national associations of statutory health insurance funds went along with BVMed's recommendation to refrain from stipulating reference prices for draining incontinence products for the time being is also considered positive. This was due to the partial lack of similarity and equal value in the function of these products with regard to the assignment of reference price groups. Private additional payments of up to 200 Euros would have been the result. The stipulation of reference prices for draining incontinence devices will thus be postponed until product group 15 of the medical technical aids register is updated.



Peritoneal Dialysis



Rheopheresis performed in Outpatient Treatment



Tube Bandage



Mobile Insuline Pumps

## Homecare

### Increase Appreciation of Homecare

Legislative bodies and statutory health insurance funds still fail to take the growing significance of homecare as a new sector of care into account. In contrast to the strict distribution of technical aids, homecare is characterized by the qualified and professional provision of advice and support on the use of technical aids in need of illustration, often in combination with drugs, dressing materials or medical devices that are subject to sale by pharmacies only.

Homecare services are almost exclusively financed via product compensation and the reimbursement of technical aids in particular. Decreasing reference prices and a price determination considering nothing but the cost of the product put this sector of healthcare, which represents a crucial link between the pure supply of products and the treatment and care of patients in their own home environment, increasingly at risk. The rising tendency towards flat-rate reimbursement also endangers an appropriate and patient-individual care.

### Pressure on Prices and Administration Costs

Particularly smaller, local homecare companies suffer from the severe price competition among care providers at simultaneously increasing administrative costs arising from co-payments, sickness fund individual reimbursement procedures, the conclusion of individual contracts due to the general agreements' shrinking in significance, participation in tenders, and so on. It is as yet unclear how the introduction of an electronic prescription as part of an electronic health insurance card, would affect the homecare market. However, the implementation of the necessary technology will unquestionably result in considerable extra costs for care providers.

Ultimately, the sometimes vague phrasing of legal requirements and their varying interpretation on the part of sickness funds can only be resolved by the social courts. However, the relatively long duration of legal proceedings of an average 15 months does not provide care providers with the prompt legal protection they require.

Nevertheless, the GMG also offers a positive potential for development for the homecare sector. The amended § 139 of the German Social Code, Book Five, according to which the national associations of SHI funds issue product-category based recommendations for the training of technical aids providers and for the quality assurance of the care provided, offers the opportunity of distinguishing homecare from the pure distribution of technical aids. BVMed went along with the suggestion of the national associations of SHI funds and has already compiled several proposals. The planned change in nurse training also pays due respect to the growing need of qualified professional homecare services rendered by registered nurses.

### New Models of Care: Integrated Care and Medical Healthcare Centers

With the GMG, the development of new healthcare structures gained additional momentum. Legal requirements for the conclusion of integrated care agreements were deregulated and allow for individual agreements between sickness funds and care providers. Thus, homecare companies can now become contracting parties, too. Manufacturers can indirectly get involved in integrated care in the form of management companies. The start-up financing provided for by the GMG triggered a downright contracting race among sickness funds. More than 200 contracts were concluded in 2004 – however – they differ significantly in terms of the character and extent of care agreed upon. The following healthcare areas are predominant: endoprosthetics, cardiovascular surgery, interventional cardiology / care for the chronically ill, coronary heart diseases, hospital-based outpatient care according to § 115 b of the German Social Code, Book Five, as well as breast cancer diagnostics and therapy, which are mainly reimbursed via complex flat-rates.

In contrast to integrated care agreements, implementation of medical healthcare centers has started somewhat sluggishly. The law does not provide for the involvement of industry or trade companies. Nevertheless, it is apparent that many homecare companies and providers of health supplies perceive cooperation with medical healthcare centers as an important strategic market positioning tool.



Mobile Infusion Pump



Micro-Stimulation System for Perception Support and Pressure Ulcer Therapy



Antidecubitus Mattress

## Medical Device Legislation

### MDD Revision

At European level, the revision of the directive 93/42/EEC on medical devices (Medical Devices Directive, MDD) represented the main subject of discussion within the European “Medical Devices Experts Group” (MDEG), which is made up of national government representatives. A first draft of the revised directive was presented by the European Commission on 1 October 2004. The draft directive will be published in the European Official Journal in the spring of 2005. The amended directive may come into effect at the end of 2005.

This amended directive will provide for a tightened regulatory environment, particularly with regard to the clinical evaluation of medical devices. Furthermore, notified bodies shall be enabled to assess the product design of medical devices more intensively, either by an amendment of the conformity assessment procedures or by a reclassification of particular product groups. The reclassification of particular joint implants from class IIa to class III has not yet been executed. The enforcement of a Commission directive on the reclassification of these joint implants is still under way.

In the course of the EU Commission’s reorganization, regulatory responsibility for the sector “Medical Devices” within the Enterprise Directorate General is being reassigned. Thus, the sector’s economic and health political significance is taken into due account.

### Legal Development in Germany

The only German legislative activity with regard to medical devices in 2004 was an amendment to the Medical Devices Ordinance (Medizinprodukte-Verordnung – MPV), which was required to nationally transpose directive 2003/32/EC on medical devices that are manufactured by utilizing animal tissues.

The revision of the Ordinance on the Operation of Medical Devices (Medizinprodukte-Betreiberverordnung – MPBetreibV) which, among other things meant to define who is the responsible operator of medical devices, remains in preparation. Furthermore, the legal regulations on the advertisement for medical devices, codified in the Act on Advertising in the Healthcare

System (HWG), are to be amended. From industry’s point of view, a less ambiguous regulation on advertising via the distribution of medical device samples is called for.

### Objection to Additional Assessments of Medical Technical Aids

From the view of medical device legislation, the fact that the national SHI associations’ heads of department responsible for technical aids keep demanding overlapping assessments of the performance of products which are compliant to the legal requirements of the Medical Devices Act (MPG) is critical. Instead of accepting conformity assessment procedures based on a full quality assurance system, they often requested execution of a product assessment which is entirely unsuited for the mass production of medical consumer goods. Occasionally and even as recent as in 2004, employees of the national associations of SHI funds demanded the execution of a “GS assessment” (“GS” stands for “Geprüfte Sicherheit” = “certified safety”) for medical devices, thus conflicting with the Medical Devices Act.

A further demand on the manufacturers of medical technical aids is the additional proof of a “therapeutic benefit”, regardless of the fact that the purpose of almost all technical aids is not therapy (treatment of diseases) but the compensation for and alleviation of physical disabilities. The confirmation of a medical device’s technological performance must already be provided according to the Medical Devices Act and is furnished by an obligatory clinical evaluation. The legitimacy of the CE marking on medical devices confirming their safety and performance must not be challenged without due suspicion of the opposite.

To the relevant representatives of health policy, the national associations of SHI funds and the Federal Ministry of Health, BVMed pointed out the contradictory nature of the requirements of the older Social Code, Book Five, in comparison with the more recent Medical Devices Act. The Medical Devices Act came into effect ten years ago, on 1 January 1995.



Prevention of Sharps' Injuries by Use of Safety Products



Orthopedics and Surgical Standard Applications



Glaucoma Scalpel



## Patient and User Safety and Environmental Issues

### Re-use of Medical Devices

The re-use of medical devices developed and labeled by the manufacturer for single use only remains a delicate subject. In such cases, liability for any consequential damage arising from this practice rests with the employers in medical facilities and the medical staff. When stipulating more stringent requirements for the reprocessing of medical devices in 2002, legislation had taken the operators' and users' high level of responsibility into due account.

Taking stock of the past developments, MedInform's conference in October 2004 showed that implemented measures are beginning to take effect. The so-called "RKI recommendation" represents a high-level guiding principle for the quality of reprocessing. The targeted monitoring of reprocessing activities has meanwhile led to the shutting down or improvement of reprocessing plants. The possibility of obtaining certification from external bodies for the reprocessing of high-risk devices according to the RKI recommendation is widely accepted. When it comes to the reprocessing of single-use medical devices, the demand for the future is that manufacturers and reprocessors must adhere to the same requirements and undertake conformity assessment procedures. And: Monitoring of reprocessing activities by the relevant authorities must be reinforced.

Next to the reprocessing of single-use devices, the often insufficient reprocessing of devices intended for multiple use is increasingly often in the focus of attention. Manufacturers are obliged to provide information on suitable reprocessing procedures for their multiple-use devices. These are, mostly for financial reasons, often ignored – at the patients' expense. Therefore, BVMed presented a "Guideline for the Reprocessing of Suction Devices" (German language only) for tracheotomized patients in January 2005.

### Prevention of Sharps' Injuries

The safety of medical devices also comprises the protection of users. Medical staff are particularly at risk of infection, often caused by injuries with pointed or sharp instruments. The technical guideline "biological working materials in healthcare and welfare" (TRBA

250) issued in 2003 provides for the replacement of "sharp, pointed or fragile devices by such suitable devices or procedures that involve no or next to no risk of stab and incision wounds". BVMed's member companies offer a number of devices which help reduce the risk of sharps' injuries to a minimum if used according to instructions. However, application of these safety devices is still hesitant.

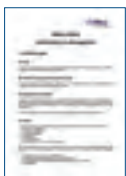
At the "Safety Symposium" in February 2005, users and representatives of BVMed and the relevant accident insurance companies jointly looked into the question "What has been achieved by the implementation of the technical guideline TRBA 250?".

### Environmental Issues

Two comprehensive bodies of legislation appeared on the agenda in 2004: the EU Chemicals Policy and the European and national regulations for waste electrical and electronic equipment. The implications of this new legislation for the medical devices industry cannot yet be fathomed. A workshop of BVMed in May 2004 provided the association's members with the opportunity to come to terms with the new challenges.

### Bar Codes

Auto-identification systems for medical devices such as bar codes receive more and more attention. Next to their acknowledged capacity for logistic benefit they are increasingly regarded as a means for increasing patient safety. Still, bar codes are only used reluctantly. All in all, universal application of bar codes from the manufacturer to the patient is still a long way off. In order to pave the way for this useful instrument, BVMed's relevant sub-group published a brochure entitled "Barcodes on Medical Devices" (also available in English), which provides an overview of the possible ways of using bar codes and describes the technical environment as well as various types of bar codes, in short: a guide for "newcomers" to this complex subject.





BVMed Press Seminar in Berlin



BVMed Booth at Capital Congress



Shooting for BVMed's TV Service

## Communications / Press

Communication to patients is rapidly gaining in importance. For informing the public at large about the significance of medical technologies and new medical technology products and therapies we need the mass media.

### TV Service Medical Technology

In the autumn of 2004, BVMed launched its "TV Service Medical Technology" at [www.tvservice.bvmed.de](http://www.tvservice.bvmed.de). The objective of this new service is to improve the positioning of medical technology issues in television. BVMed's TV service provides professional footage, including original statements, which may be used by TV broadcasting companies free of charge. Several first releases have already been broadcast by news and regional channels. Next to footage, complete films on innovative medical technology therapies – presented via patient stories – can be downloaded from the internet or ordered on DVD. This is of particular interest to teachers or other information disseminators. The films and footage are available free of charge for all interested parties.

### PR Campaign "Aktion Meditech"

The PR campaign "Aktion Meditech", initiated by BVMed and Advamed, involves doctors and patients, individuals, groups, companies and associations. The campaign has made it its business to inform on new treatment methods in medical technology and to ensure that affected patients get a chance to participate in healthcare policy. With its intensive media work in 2004, Aktion Meditech achieved more than 80 million readers via 150 articles in yellow press magazines. Further activities consisted of the first "Patient Group Symposium", a press seminar, a "decision-maker event" for politicians and representatives of hospitals and sickness funds, as well as a [quarterly newsletter](#). All subjects and information can be found on the internet at [www.aktion-meditech.de](http://www.aktion-meditech.de).

### Media Work and Image Cultivation

While Aktion Meditech continues to attract a lot of yellow press attention, BVMed's media work concentrates on the trade, daily and economic press. 2004's media tools were, among others, press releases, press conferences, articles and contributions for magazines as well as media cooperations. 108 million reader

contacts could be achieved with some 600 articles, which represents an increase of more than 20 per cent compared to the year before. The continuous supply of information is supplemented by weekly newsletters, an e-mail service providing the latest news and developments, as well as by press releases and monthly BVMed reports in English.

For the positive promotion of the medical technology sector's image BVMed carried out further projects, such as its own booth at the Capital Congress in Berlin in July 2004, its press seminar on the "Trends in Medical Technology" in November 2004 as well as the publication of its brochure "[History and Trends in Medical Technology](#)", which can be ordered free of charge (German language only). On top of that, BVMed is actively involved in the image campaigns "Vitale Gesellschaft" (vital society – [www.vitale-gesellschaft.de](http://www.vitale-gesellschaft.de)) of the federal association of German industry, BDI, and "Health First" ([www.healthfirsteurope.org](http://www.healthfirsteurope.org)) of EUCOMED.

### Internet and Extranet

BVMed's German and English internet pages at [www.bvmed.de](http://www.bvmed.de) were modernized in the fall of 2004 and recorded more than 9 million hits in total, which stands for an increase of 60 per cent over the year before. In December alone more than 1.2 million hits and 428,000 visits were registered. Compared to December 2003, this number has tripled. The average visiting time spent on the more than 5,000 individual internet pages of BVMed amounted to some five minutes. Each visitor accessed an average 10 sub pages, which highlights the high quality and comprehensiveness of BVMed's website. For its member companies, BVMed further enhanced its extranet as a central information and communication platform. A new content management system, introduced in the fall of 2004, keeps internal communications at an up-to-date level.

### 7th E-Commerce Conference

With its so far 7th E-Commerce conference in February 2005 on topics of electronic procurement, BVMed established an "E-Procurement get-together" and an information and communication platform for hospitals, manufacturers and service providers.

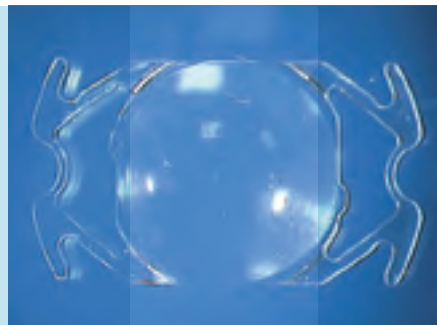




Intraocular Lenses for Cataract Treatment



Foldable Micro Incision Lens



Aspheric Lens – Improved Contrast Sensitivity in Varying Light Conditions



Phakoemulsification for Cataract

## Reports from BVMed’s Expert Committees

In 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

#### Focus Groups

Healthcare Systems

Legal Issues

Regulatory and Public Affairs

Environment

Electronic Communication in the Healthcare Market

#### Focus Group “Healthcare Systems” (AKGS)

AKGS addresses systemic issues related to reimbursement, distribution channels, health economic considerations or medical technology assessment. In addition, the group analyzes and evaluates legislative procedures as well as policy initiatives and prepares statements for hearings. The implementing provisions of the SHI Modernization Act represented one of the focus group’s main topics in 2004. For the further development of the healthcare system, AKGS produced a health political position paper. Furthermore, the group prepared a statement on the 2nd DRG amendment law and supported the compilation of a DRG expert report by Professor Dr Neubauer. In addition, AKGS devised concepts for a conference on Health Technology Assessment and for BVMed’s 5th Innovation Congress.

#### Focus Group “Legal Issues” (AKR)

This focus group is in charge of updating and editing BVMed’s “WiKo–Commentary on Medical Device Legislation” (ISBN 3-504-04002-5). At the end of 2004, the commentary was complemented by a supplement and a new case-law overview on CD-Rom featuring some 150 court rulings on medical devices. Furthermore, AKR addressed the legal issues brought to its attention by BVMed’s board or expert committees, monitored the national implementation of the European

directive on the Community code relating to medicinal products for human use, and urged the relevant authorities to improve the legal framework for the advertising for medical devices (HWG), thus aiming at the introduction of a legal provision allowing for the distribution of samples of medical devices. AKR holds joint meetings with the members of the “Network Medical Devices”, a group of presently nine lawyers.

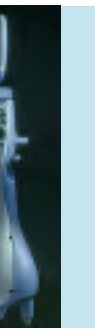
#### Focus Group “Regulatory and Public Affairs” (AKRP)

AKRP held four meetings in 2004. Moreover, a subject-related exchange of information took place within the ten sub-groups of AKRP. Key tasks and issues of this focus group are: exchanging ideas and experience with the Federal Ministry of Health and the Federal Institute for Drugs and Medical Devices on the revision of the European directive on medical devices, particularly on key issues such as E-Labeling and the reclassification of new product categories; continuous updating of BVMed’s information series “Medical Device Legislation”; organization of the events “Quality Management Systems”, “Practical Implementation of the Medical Devices Act”, and “Consultation Process for Medical Devices Containing Pharmaceuticals”.

#### Focus Group “Environment” (AKU)

In 2004, this focus group addressed the key issues “legislation on waste electrical and electronic equipment” and “EU Chemicals Policy” (REACH). On 13 August 2005, the German Electrical and Electronic Equipment Act will come into effect. By the end of 2004, the members of the sub-group AGE had only been provided with a cabinet draft. On this basis, the group designed a recommendation for BVMed’s members providing advice on the implementation of the regulation for “potentially infectious” and “application-related potentially infectious” medical devices, administration with regard to private consumers and in the commercial area, as well as notification and information requirements. The consequences of the new European legislation on chemicals are even harder to assess, but might, at the same time, have even more far-reaching implications. It is feared that well-established substances will disappear from the market.





Classification System  
at Extraction



Instrument for Gentle Treatment of Hemorrhoids



Mammary Implants Filled with Silicone Gel

### Focus Group

#### “Electronic Communication” (AKEKOM)

In 2004, AKEKOM's sub-group “Barcodes” compiled a brochure advising member companies on the use of “Bar Codes on Medical Devices”. This comprehensive publication provides interested manufacturers with a solid overview on where and how bar codes can be applied and used and describes the technical environment as well as the various types and symbologies of bar codes. Since many of the brochure's statements also apply beyond the German language area, it was published in English as well.

### Sectoral Interest Groups

#### Sectoral Interest Group “Bandages” (FBB)

In agreement with the federal association of guild health insurance funds (IKK-Bundesverband) and the medical service of health insurance funds, BVMed and EUROCOM jointly work on a draft for the product group 23 “Orthotics/Splints” of the medical technical aids register. Further key issues are the re-use of orthotics and problems relating to value added tax.

#### Sectoral Interest Group “Blood” (FB Blood)

FB Blood comprises manufacturers of blood bags and devices for apheresis. The group addressed the requirements of the Transfusion Act on quality and safety standards for the collection, processing, storage and distribution of human blood and blood components and incorporated its position into the work of the European committee of manufacturers. FB Blood felt particularly affected by considerations of environmental associations and authorities of withdrawing well-established and hitherto irreplaceable materials from the market in anticipation of the planned European legislation on chemicals and pleaded for a benefit / risk assessment oriented towards the best possible patient care.

#### Sectoral Interest Group “Brachytherapy” (FBBT)

The working group “Interstitial Brachytherapy” (PG IBT, Seed method) of the sectoral interest group FBBT promotes the adoption of this gentle form of therapy in outpatient care. The assessment procedure of the Federal

Joint Committee is supported with statements. Applications for the depiction of intracoronary brachytherapy in the DRG system were filed and will be introduced into the DRG catalogue in 2005 for the first time.

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

Internationally increased awareness of the demands on emergency medicine also influenced the standardization work relating to “dressing materials and containers” and the range of topics of this sectoral interest group, which represents the manufacturers of first aid kits and medical emergency equipment. Thus, the update of first aid materials according to the latest findings in emergency medicine dominated the group's work. FBEH's sub-group “Communication” (AGK) reminds users of the underestimated contents of their car's first aid box and of ways of providing fast and efficient first aid.

#### Sectoral Interest Group “Medical Technical Aids against Decubitus Ulcers” (FBHD)

FBHD seeks to increase awareness of the sensitive issue of “decubitus ulcers” and the associated challenges by way of targeted public relations work. These activities will be supported by the newly prepared brochure “Selecting the Proper Decubitus Aid”.

#### Sectoral Interest Group “Homecare” (FBHC)

This group aims at an unambiguous definition of the term “homecare” in the expert community and at establishing the term as “therapy at home” to achieve a demarcation from “outpatient care”. For this purpose, FBHC is preparing a position paper emphasizing the significance and necessity of homecare and providing approaches for ensuring an appropriate care of patients in the future. The incorporation of homecare into new models of care is considered a great opportunity for the development of the homecare market. The group compiles information on integrated care (IV) and medical healthcare centers (MVZ) and maintains contact to other partners in the healthcare system.

### Sectoral Interest Groups

- Application Aids
- Bandages
- Blood
- Brachytherapy
- First Aid Materials
- Ethylene Oxide Sterilization
- Medical Technical Aids against Decubitus Ulcers
- Homecare
- Infusion Therapy
- Intraocular Lenses
- Cardiovascular Medical Devices
- Compression Stockings
- Artificial Feeding
- Health Insurance Law for Care Providers
- Medical Technology Implants
- Minimally Invasive Procedures
- Modern Wound Care Products
- Absorbing Incontinence Care (Manufacturers)
- Consultation Overheads, Practice Supplies, Medical Dressings
- Supply of Sterile Products
- Ostomy/ Incontinence Care
- Radiation Sterilization
- Therapeutic Apheresis
- Tracheostomy/ Laryngectomy
- Spine Surgery



Navigation System for Endoprosthetics



Hip Joint Implant with Navigation System



Surface Hip Replacement



Knee Joint Prosthesis

### **Sectoral Interest Group “Intraocular Lenses” (FBIOL)**

In 2004, the members of this group reinforced their cooperation with ophthalmologists. In various round-table talks with leading ophthalmologists, the group determined opportunities for cooperation. Key issues were the appropriate reflection of costs in the outpatient and inpatient sector as well as the demands on an efficient and adequate quality assurance in cataract surgery. As in the past years, FBIOL continued to be actively involved in trade fairs and conferences in the field of ophthalmology.

### **Sectoral Interest Group “Cardiovascular Medical Devices” (FBKMP)**

FBKMP's objective is to ensure appropriate reimbursement for innovative cardiovascular medical devices in both inpatient and outpatient care. Its activities comprised, among others, regular contacts to the relevant medical expert society (German Cardiac Society, DGK) and its committees for the further development of DRGs. At the society's autumn meeting, the group also organized an expert symposium on the subject: “How will the G-DRG hospital flat-rate reimbursement system affect innovative cardiology in the future?”

### **Sectoral Interest Group “Artificial Feeding” (FBKE)**

The revision of the pharmaceutical guideline on the reimbursement of drink and tube feeding planned by the Federal Joint Committee represented the main focus of this sectoral interest group. BVMed and other relevant associations entitled to attend the committee's hearings jointly submitted a statement. From a legal, medical and ethical point of view, the draft presented by the Federal Joint Committee cannot be approved of, which is why an approach to solution emphasizing malnutrition resulting from illness as an essential prerequisite for reimbursability was submitted by the group. Next to the stipulation of quality standards for enteral feeding (according to § 139, para. 3 of the German Social Code, Book Five), FBKE also addressed the ongoing dispute on the value added tax level for drink and tube feeding as well as the current market development.

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

FBLL addresses the current questions of member companies relating to the provision and reimbursement of healthcare services within the legal framework of interrelation among sickness funds, care providers and patients, particularly in view of the healthcare reform. Further tasks of the group are to update BVMed's compilation of court decisions available at [www.bvmed-sozialrecht.de](http://www.bvmed-sozialrecht.de) and to establish a network of social-law experts. Regular exchange of information is provided by means of the group's newsletter “Blick. Sozialrecht” (in focus: social legislation). In November 2004, a special event for judges of the social courts on tenders in the technical aids sector was carried out for the first time.

FBLL's sub-group “Legal Issues” was concerned with complex legal matters, such as the tendering procedures for health insurance funds provided for by the GMG. Owing to the contradiction in public procurement law and social legislation, and in order to achieve a uniform implementation of the tendering procedures in the technical aids sector stipulated by law, this sub-group worked out a set of implementation rules, which was presented to the Federal Ministry of Health and will be discussed with the national associations of statutory health insurance funds.

### **Sectoral Interest Group “Medical Technology Implants” (FBMTI)**

One central task of this sectoral interest group was to establish how the introduction of the DRG system in German hospitals will affect the endoprosthetics industry. FBMTI's key activities also include the introduction of an endoprostheses register in cooperation with the Federal Office for Quality Assurance (BQS) as well as congress management. On top of that, the group initiated the campaign “Orthopädie bewegt” (“orthopedics move” – [www.orthopaedie-bewegt.de](http://www.orthopaedie-bewegt.de)) in a joint effort with the German orthopedic societies.

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

The most important topic for this group was the prescribability and reimbursability of dressing materials,



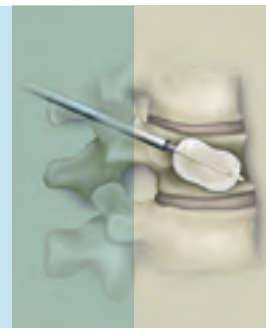
Total Ankle Joint Replacements



Acetabular Cups made of Material Similar to Cancellous Bone



Intramedullary Nail for the Stabilization of Femoral Fractures



Kyphoplasty for Treatment of Vertebral Fractures

and of products for modern wound care in particular. The introduction of the SHI Modernization Act caused significant insecurity among all parties concerned on whether these products – along with non-prescription drugs – would cease to be reimbursable. This was not least due to deficient software in doctor's offices. In various public relation measures, FBMW pointed out that dressing materials remain prescribable and must still be reimbursed by Statutory Health Insurance. The group also updated the brochure on the prescribability and reimbursability of wound care products.

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

In the context of the introduction of federal reference prices FBI was committed to maintaining the quality of care and to securing adequate reimbursement of the required products. Thus, the group achieved an increase of the proposed reference prices.

#### **Sectoral Interest Group “Consultation Overheads, Practice Supplies, Medical Dressings” (FBSRV)**

FBSRV stepped up its talks with sickness funds and doctors' associations on the subject of “reimbursement of material costs for office-based SHI physicians”. The introduction of the new reimbursement catalogue “EBM2000plus” and its potential impact on material costs due to the intended implementation of a new section on material costs remained in the focus the group's work.

#### **Sectoral Interest Group “Supply of Sterile Products” (FBSV)**

Specific questions relating to the requirements on sterile products and their application are followed up in FBSV's sub-groups if required. The sub-group “Supply of Sterile Products” (AGSV) is concerned with the convergence of European and international standards for sterile product packaging. Questions relating to the handling of potentially contaminated returned medical devices are answered by the sub-group “Returns”. The sub-group “Catheters” (AG KATH) is a forum for users and authorities seeking particular information on catheters. The sectoral interest groups “Ethylene

Oxide Sterilization” (FBEO) and “Radiation Sterilization” (FBS) address specific sterilization procedures.

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

The introduction of federal reference prices for ostomy and incontinence aids marked this group's work in 2004. By means of in-depth expert statements and the concerted action of all affected associations (manufacturers, care providers, patients), a temporary suspension of reference prices for draining incontinence aids as well as an improvement in the proposed reference prices could be achieved.

#### **Sectoral Interest Group “Therapeutic Apheresis” (FBTA)**

FBTA's members are providers of technologies for extracorporeal blood cleansing who, in 2004, continued in their quest for appropriate reimbursement of their innovative technologies. Approval of apheresis therapies is greatly impeded by the fact that these technologies are often successfully used in the treatment of rare diseases, so-called “orphan diseases”, thus rendering a customary statistical assessment inapplicable. FBTA is committed to improving the state of available data in this area.

#### **Sectoral Interest Group “Tracheostomy / Laryngectomy” (FBTL)**

Main subjects of this group were the update of product group 12 “technical aids for tracheostomy”, the GMG's impact on tracheostomy care, problems encountered when applying for a registration number for the medical technical aids register, as well as the reprocessing of suction devices. Furthermore, FBTL published a “Guideline on the Care of Tracheotomized and Laryngectomized Patients” (German language only).



#### **Sectoral Interest Group “Spine Surgery” (FBSC)**

The agenda of this newly established sectoral interest group includes the development of guidelines as well as proposals for an appropriate reflection of various surgical procedures on the spine within the DRG reimbursement system for hospitals.



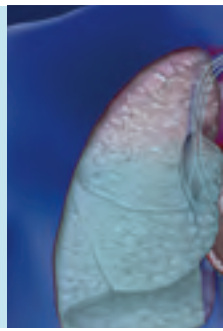
Triple-Chamber Pacemaker



Pacemaker with Home Monitoring Service



CRT-Defibrillator with Automatic Monitoring of Fluid Accumulation in the Lungs



### Working Groups

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

## Working Groups

### Working Group “Peripheral Vascular Intervention” (PG PVI)

The companies organized in this working group established a prospective register (PTA-REG) for the recording and post surgical observation of patients suffering from peripheral occlusive arterial disease before or after undergoing PTA in cooperation with three medical expert societies.

### Working Group “Re-Use” (PG Re-Use)

Since more binding requirements on reprocessing were incorporated into German Medical Device legislation, PG Re-use has pursued the objective of achieving an unambiguous governing of the re-use of single-use medical devices within the European Medical Devices Directive. The group proved successful in its cooperation with patient associations. In future, reprocessing of medical devices intended for multiple use will assume an important role in BVMed’s work as well. Thus, one of BVMed’s working groups published a guideline on the “reprocessing of suction devices”, which was distributed among providers of medical supplies and sickness funds. The ensuing positive response shows that there is also a great need for action for multiple use devices.

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

By submitting proposals for an appropriate reflection of innovative and established medical technologies, this working group supports the restructuring of contractual arrangements on outpatient surgery conducted by office-based physicians as well as in hospitals according to § 115 b of the German Social Code, Book Five. Reimbursement of material costs for medical devices in office-based outpatient care is also in the focus of the group’s activities.

### Working Group “Sets” (PG Sets)

PG Sets is committed to securing a uniform SHI-reimbursability of catheter sets in outpatient care. In various talks, the group’s experts brought this issue to the attention of politicians and representatives of sickness funds as well as patient groups.

### Working Group “Tissues” (PGT)

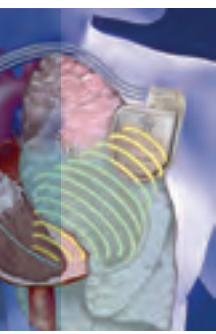
The most important issue for this working group was the implementation of the European Directive 2003/32/EC on TSE-relevant medical devices, which was incorporated into German legislation on a one to one basis. PGT also addressed the regulatory framework for products incorporating tissues or cells of human origin, so-called “human tissue products”.

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

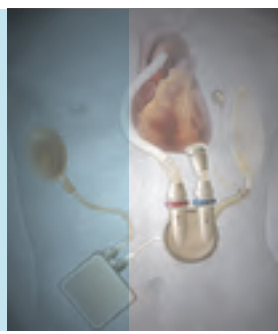
This working group supports the implementation of innovative cardiac support systems as well as of cardiac replacement technologies (artificial hearts). A coding tool for the assignment of technologies in the DRG classification system was developed. At a congress of the German Cardiac Society in Mannheim, this technology was presented to cardiologists in the course of a scientific symposium. A conference on the reimbursement of cardiac and cardiovascular support technologies illustrated an appropriate reflection of these innovative technologies in the new G-DRG flat-rate reimbursement system.

### Working Group “Sharps Injuries” (AG NSV)

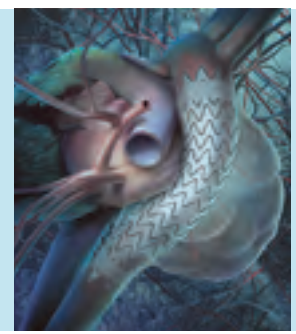
The manufacturers of safety products within this working group demonstrated their commitment to a consistent implementation of existing laws and regulations on the prevention of sharps injuries in various publications and round tables with politicians and representatives of occupational health and safety authorities. Injuries with pointed or sharp instruments pose one of the greatest risks of contracting hepatitis infections and HIV. Increased networking of users and accident insurers, authorities and manufacturers gives rise to the hope that the application of existing knowledge and available means will gain momentum.



Implantable Artificial Heart



Implantable Cardiac Support System



Endoprosthesis for "Repairing" the Aorta

## Outlook

# Nine Theses on Health Economy

In the long term, only a fundamental reorganization of the healthcare system with increased competition and market orientation can secure an affordable, high-quality healthcare. The German healthcare system can only gain in dynamics if it is freed from excessive bureaucracy and allowed to benefit from deregulated and liberalized healthcare markets.

BVMed presents the following nine theses on "health economy 2005 plus: conflict of solidarity and market" to help reshape the debate on the future business environment for the companies of medical technology.

### 1. Impact of Medical Technologies

The value of innovative medical technologies must be more strongly appreciated in German healthcare. Medical technologies can contribute to an altogether more effective healthcare system. They lead to shorter recovery times and enable patients to return to work more quickly, thus creating economic gain that must no longer be ignored.

### 2. Health Policy

Health policy must provide incentives for innovation. One essential goal of the health insurance reform must be to provide all patients with access to the medical advances and medical technological innovations they require without delay.

### 3. DRG System

The new hospital reimbursement system must be open to new treatment methods. We require flexible and non-bureaucratic solutions among contracting parties at a local level. Only if the imposition of budgets is ended can this system lead to more transparency and performance-oriented reimbursement, thus allowing the healthcare system to focus on patients' needs.

### 4. Health Technology Assessment

The Joint Federal Committee's procedures of Health Technology Assessment (HTA) must be clear and transparent. HTA methodologies must be harmonized throughout Europe to allow for efficient compilation of data and rapid release of assessment outcomes. Industry must be more actively involved in the process.

In order to achieve this, industry should be able to file applications, have a say in HTA procedures (case-related introduction of experts) and raise objections to challenge negative decisions (see page 18 for more information on HTA).

### 5. Medical Technical Aids Sector

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

### 6. Homecare

Homecare serves the health political aim of "outpatient before inpatient". Therefore, adequate conditions must be created for this growing healthcare sector. Homecare improves patients' quality of life. The qualified and professional provision of advice and support on the use of technical aids in the treatment patients must be taken into due account.

### 7. Outpatient Remuneration System

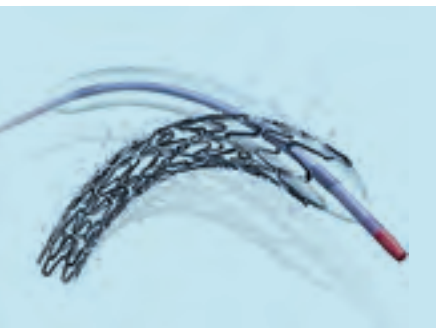
In the outpatient sector, we need a reform of the remuneration system that allows for a fair and appropriate reimbursement by statutory health insurance and reflects the true material costs incurred in a treatment. Patients must be allowed a range of options to take on more financial responsibility when it comes to innovative procedures.

### 8. Healthcare Research

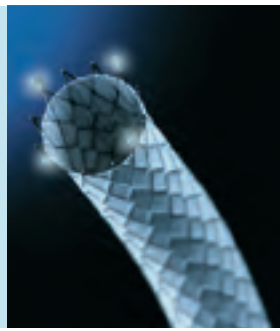
In order to be able to portray the total costs of a therapy as well as its benefits for patients and the economy, we need increased healthcare research. The assessment of new procedures must be outcome-oriented.

### 9. Strengthening of Patients' Rights

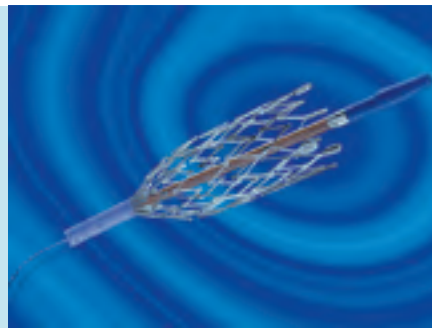
Patients' individual responsibility for their own health must be supported by way of new, flexible and optional financing models.



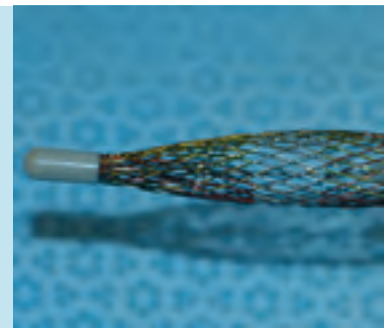
Coronary Stent



Vascular Stent with Radiopaque Markers



Nitinol Stent Implantation System



Ablation Catheter

## Side Glance

# Four Demands on the Federal Joint Committee

One of the Federal Joint Committee's (G-BA) tasks is to perform technology assessments with the assistance of the newly established "Institute for Quality and Cost-Effectiveness in the Healthcare System" (IQWiG). This means that new or existing methods of diagnosis or treatment intended for inpatient care must undergo an evaluation of their benefit and efficacy before they can be reimbursed by the statutory health insurance funds. In English-speaking areas, this is called "health technology assessment", in short: HTA. Industry considers health technology assessment a useful and relevant tool yielding valuable information. From BVMed's point of view, however, this would presuppose an implementation of the following four requirements in the G-BA's and IQWiG's future work:

### 1. Clear requirements and swift procedures

Manufacturers need clear and appropriate requirements on what will be assessed in which manner in HTA procedures. In that case the Federal Joint Committee's procedures can also be concluded more rapidly.

### 2. Increased transparency and improved industry participation

What we need is transparency, an end to discussions behind closed doors. Involving the patients' associations was a first step in the right direction. In order to be able to assist the Federal Joint Committee in its deliberations with in-depth know-how and expertise, the medical devices industry must be actively involved in the entire process. This would, however, presuppose an according scope for application, co-determination and objection.

As a first step, BVMed suggests increased industry participation in assessment procedures in the shape of a "case-related nomination of experts".

*BVMed's proposal envisions the following:*

:: As soon as a request for the assessment of a method or technology is received by the Federal Joint Committee, information on the particular applications is communicated to the industry and trade companies. In this case, BVMed is prepared to establish a "coordination com-

mittee medical technology" which would also comprise further industry associations from this area, thus allowing for a representation of the entire medical devices industry.

:: Upon receipt of an upcoming request for assessment, this "coordination committee medical technology" will promptly agree on the nomination of a medical expert for the procedure in question, who will support the Federal Committee in an advisory capacity and participate in the relevant sessions or hearings.

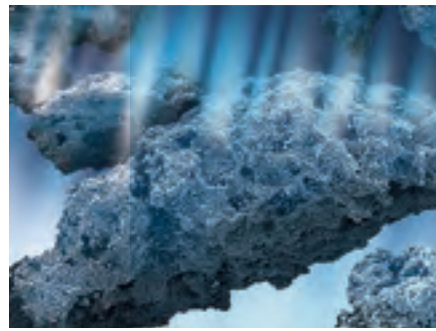
This would be a significant step forward towards more openness, transparency, and acceptance.

### 3. Adherence to an exception clause for bans on medical technological innovations in hospitals

Medical technological innovations in hospitals are subject to reimbursement by statutory health insurance, unless there has been a negative decision of the G-BA. This principle in inpatient care must remain applicable to provide all patients with access to the medical technological innovations they require without delay. This is primarily true for the hospital sector, as many innovations come into application in clinical routine. As early as in the annotations to the law, legislature refers to the deliberate innovation-friendly regulation for the acute inpatient care sector (BT printed matter 14 /1245, page 90)! In addition, an innovation clause was rightly established in the new flat-rate reimbursement system to allow for a timely and appropriate financing of innovations.

### 4. Harmonization / Recognition

The assessment of medical technologies, and new treatment methods respectively, must be harmonized across Europe or at least secured by mutual recognition procedures. Medical technology companies are increasingly active at an international level. It is inconceivable that different requirements apply in Europe. Therefore, it is an important task for the Federal Ministry of Health to work towards uniform criteria across Europe.



Open-Pore Prosthesis with “Honeycomb-Like” Structure for External Scaffolding in Vascular Prosthetics

Intracranial Stent for Blood Vessels in the Brain

New Methods in Medical Technology: Porous Resorbable Bone Void Filler for Bone Regeneration

Collagen for use in pelvic floor reconstruction

## Side Glance

# Trends in Medical Technology

The development of medical technology in the last decades of the 20th century was incredibly dynamic. Synthetic single-use devices, joint replacements, pacemaker technologies or minimally invasive procedures made for a high standard in medical technology care. But despite all these advances, we must realize that we are now on the brink of a medical technology revolution.

Progress will accelerate even more, as a great variety of new technologies is emerging. Examples for these new technologies are Tissue Engineering, the development of new “intelligent” materials, integration of telemedical applications in medical technological treatment methods, minimally invasive surgical technologies and nanotechnology. Increasing integration of these technologies results in the development of sophisticated therapies which often exceed “traditional” limits and areas.

:: **Tissue Engineering** will allow damaged tissue such as skin, cartilage, bone or blood vessels to be replaced with “engineered” tissue replacements grown on bio-material “scaffolds”, frequently based on the patient’s own cells or tissues, thereby greatly improving biocompatibility and the chances of better long-term prognosis.

:: **Cell Therapies** will use human cells as carriers for diagnosis and treatment. One example for this new technology are T-lymphocytes that are “engineered” to carry nanoscale metallic particles to the site of a tumor where they can be activated magnetically or by the use of light, thereby destroying the tumor.

:: **Nanotechnologies** offer the possibility to design and construct minimally invasive sensors, e.g. “lab-on-a-chip” type devices, that can perform dozens or even hundreds of analyses “in vivo” without the need for the intervention of a laboratory, thereby speeding up diagnosis and monitoring.

:: **Minimally invasive surgical techniques** are developing rapidly. The key advantages of such technologies are the decrease in trauma for the patient during treatment and significantly improved recovery times.

:: **Advanced biomedical materials** are also revolutionizing medicine. Examples of some recently-developed materials include hydro gels that greatly reduce infection during catheterization and “memory alloys” that can be used to place stents quickly and accurately.

:: **Telemedicine** allows the remote and continuous monitoring of patients, e.g. of those with cardiac implants, on a routine basis.

These examples show that modern medical technologies are the driver of the health economy and indispensable for patients’ health and quality of life. However, the advances referred to demonstrate that we are now on the brink of a medical technological revolution, which also raises ethical questions. Above all, there must be an open discussion on how timely patient access to medical technology innovations can be provided in the future.

Thus, we need a new orientation of German healthcare towards a modern and innovative health economy. This can only be achieved with a clear political will to exploit the growth and innovation potential of the German health economy.

### Order a brochure!

BVMed’s brochure “**History and Trends of Medical Technology**” (German language only) provides a comprehensive overview on the historical development of medical technology concluded with a look into the future of the branch. The 28-page color brochure can be ordered free of charge or downloaded at [www.bvmed.de](http://www.bvmed.de) (publikationen).





BVMed's Head Office in Berlin



BVMed's Annual Meeting with Chancellory Chief of Staff Dr Steinmeier and economist Professor Oberender and Professor Rürup



## BVMed – At your Service!

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Director General BVMed

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BVMed Conferences, among others with Dr Orłowski of the Federal Ministry of Health



BVMed in Dialogue with Health Minister Ulla Schmidt and Undersecretary Dr Schröder



## BVMed – Our Services for you

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

As a trade association, BVMed promotes and represents the combined interests of the medical technology industry and trade companies. In various sectoral interest groups, focus groups, and working groups, the association offers its members a platform for a constructive dialogue 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 sub-divided into four sectors:

### 1. Organization

BVMed carries out the joint formation of opinion in more than 40 committees covering specific subjects. You will find more information on the committees in this brochure starting at page 12 et seq. In the meantime, a current overview of BVMed's expert committees is available on the internet at: [www.bvmed.de](http://www.bvmed.de) (About BVMed).

### 2. Consultancy

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

### 3. Information

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

#### *Internal communication*

- :: General circular letters to all members
- :: Special circular letters for the individual committees
- :: Weekly newsletter
- :: Monthly report
- :: Extranet for member companies

#### *External communication*

- :: Website [www.bvmed.de](http://www.bvmed.de)
- :: Brochures
- :: Information cards
- :: Special BVMed conferences
- :: MedInform conferences
- :: Training seminars (Medical device consultants, seminars on statutory health insurance)
- :: Press releases and conferences
- :: Press seminar

### 4. Representation

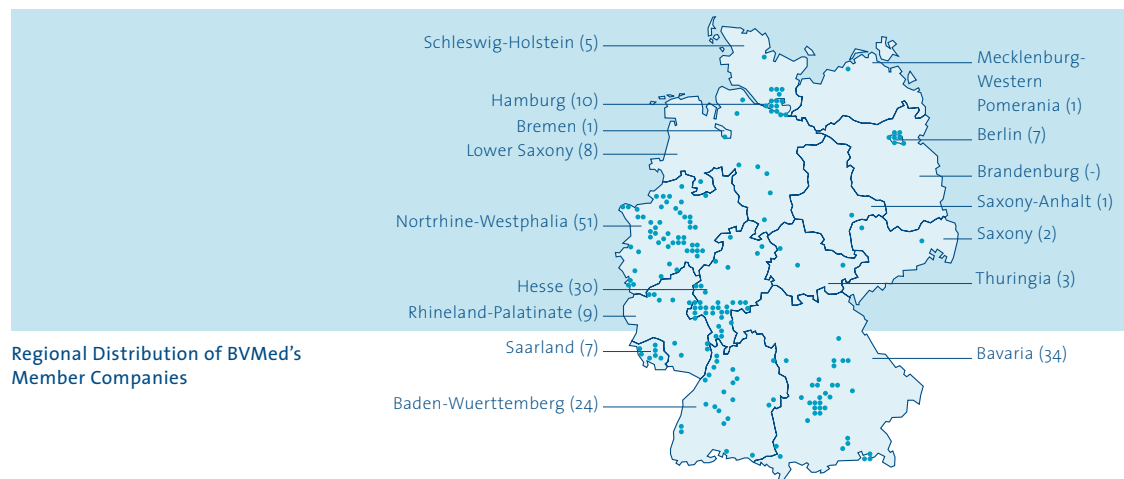
BVMed represents the interests of the medical technology sector. Important aspects are, among others:

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

#### *How can your company become a member of BVMed?*

The terms and conditions for membership of BVMed are stated in § 3 of the BVMed statutes, which you can find on the internet at [www.bvmed.de](http://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!



As on 1 March 2005: 200 members – current list available at [www.bvmed.de](http://www.bvmed.de)

## BVMed Membership List

\*3M Medica Zweigniederlassung der  
3M Deutschland GmbH

### A

aap Implantate AG  
Abbott GmbH & Co. KG  
Abbott Vasculare Devices  
Abena Hygiene GmbH  
ABIOMED BV  
\*ACRIMED Pharmazeutische und  
medizinische Gesellschaft mbH  
ACRITEC Gesellschaft für ophthalmologische  
Produkte mbH  
ADL Anti Dekubitus Lagerungssysteme GmbH  
\*AESULAP AG & CO. KG  
AirMed Prophylaxe + Therapie Systeme GmbH  
AirSystems Medizinische Produkte GmbH  
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ALPHANORM Medizintechnik GmbH  
AMEFA Großhandelsgesellschaft mbH  
für Medizin-Technik  
American Medical Systems Deutschland GmbH  
\*AMO (Advanced Medical Optics)  
Germany GmbH  
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Orthopädie-Technik  
Andreas Fahl Medizintechnik-Vertrieb GmbH  
\*Ansell GmbH  
\*ARROW Deutschland GmbH  
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Astra Tech GmbH  
ATMOS MedizinTechnik GmbH & Co. KG  
Atos Medical GmbH  
AURELIA Medical Handel GmbH

### B

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

### C

\*C. R. Bard GmbH  
Cardinal Health Germany 206 GmbH  
CareTex Medizinische Textilien GmbH  
CeramTec AG Geschäftsbereich  
Medizintechnik  
Chemische Fabrik Kreussler + Co. GmbH  
Clinical House GmbH  
Clinico Medical Production GmbH  
\*Coloplast GmbH  
Coltène / Whaledent GmbH + Co. KG  
Cook Deutschland GmbH  
CORDIS Medizinische Apparate GmbH  
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  
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### E

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

### F

\*FOR LIFE Produktions- und Vertriebsgesell-  
schaft für Heil- und Hilfsmittel mbH  
Franz Kalff GmbH  
FRESENIUS AG  
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Fuhrmann Verbandstoffe GmbH

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GARANTOL Products Detia Freyberg GmbH  
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\*GerroMed Pflege- und Medizintechnik GmbH  
\*Given Imaging GmbH  
\*GUIDANT GmbH & Co. Medizintechnik KG

### H

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Holthaus Medical GmbH & Co. KG  
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### I

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Impella Cardiotechnik AG  
INAMED Aesthetics GmbH  
INVATECH Gesellschaft für fortschrittliche  
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Isotron Deutschland GmbH

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\*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

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\*LMA Deutschland GmbH  
\*LogoMed GmbH  
Lohmann & Rauscher International GmbH &  
Co. KG  
\*Ludwig Bertram GmbH  
Lück Rhombo Medical GmbH & Co. KG

### M

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Maimed Medical GmbH & Co. KG  
Maquet Cardiopulmonary AG  
Mathys Orthopädie GmbH



Knee Brace



Hip Joint Orthosis



Hip Protectors for Preventing Fractures of the Femoral Neck Resulting from Falls



Compression Stockings

\*Medex Medical GmbH & Co. KG  
 \*medi Bayreuth Weihermüller & Voigtmann GmbH & Co. KG  
 \*Medi-Globe GmbH  
 Medical Service Vertriebs-GmbH  
 Medilog Handelsgesellschaft mbH  
 METHODIC Bernd A. Harren KG  
 \*Medtronic GmbH  
 megro GmbH & Co. KG  
 MENTOR DEUTSCHLAND GMBH  
 mepro Medizinische Produktion GmbH  
 Mundipharma GmbH  
 Mölnlycke Health Care 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

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 ORIPLAST Gebr. Krayer GmbH  
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 Otsuka Pharma GmbH  
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 \*POLYTECH-SILIMED Europe GmbH  
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**Q**

Q-MED GmbH

**R**

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 Rentex Vertriebs GmbH & Co. KG  
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 Ruth Cegla GmbH & Co. KG

**S**

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 Sangro Medical Services GmbH  
 Sanicare GmbH  
 Sanitätshaus Aktuell GmbH  
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 servoprax GmbH  
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 SFM Süddeutsche Feinmechanik GmbH  
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 Spring Medical Wilhelm Spring GmbH & Co.  
 St. Jude Medical GmbH  
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**T**

TECHNOMED Gesellschaft für med. und med.-techn. Systeme mbH  
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 The ROHO Group-ROHO International, Inc.  
 \*Thomas Hilfen für Behinderte GmbH & Co. Medico KG  
 \*THUASNE DEUTSCHLAND GmbH & Co. KG  
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 \*Wilhelm Julius Teufel GmbH  
 Willy RÜSCH GmbH

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\*Zimmer Germany GmbH

**Pictures courtesy of**

Cover: **RADI Medical Systems GmbH**  
 Intracoronary Pressure Measurement during a Coronary Angiography Procedure in a Catheterization Lab

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

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On BVMed's website at [www.bvmed.de](http://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.

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