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主旨：檢送本組蒐報德國 German Medical Technology Association (BVMed)編撰「BVMed Annual Report 2016/17」如附件，敬請查參。

說明：

一、旨述協會之創立可追溯至 1901 年，擁有 224 名企業會員(依 2017 年 3 月資料)，其中不乏世界知名醫療器材公司(名單請參閱附件倒數第 2 頁及第 3 頁)。該協會出版年報指出，會員廠商國外業務成長高於國內市場。國外業務成長約 6%，德國國內為 4%。儘管國內市場環境較為艱困，仍持續創造工作機會。2016 年醫療器材市場發展具下列特點：

(一)德國法規障礙持續增加，決策過程緩慢，歐盟對醫療器材規定所導致額外產品規範特別是對中小企業造成很大負擔。自 2011 年開始編製之 BVMed 創新指數(innovation climate index)稍微下降，會員廠商認為特別具創新力的領域為心臟病學(cardiology)、腫瘤學(oncology)及神經學(neurology)。

(二)在醫療衛生政策方面，強化醫療科技效益評估報告相互

承認及加速引進創新。

(三)66%會員廠商擴大人力招募，只有 7%廠商削減工作機會。92%年輕員工看好工作前景，工作機會較多之領域為經濟人才、工程師及醫療技工。

(四)41%會員廠商目前受數位化影響，最關切醫療 Apps 及電子採購系統(e-procurement)。

二、檢送旨述年報如附件，謹請卓參。

裝

正本：台灣醫療暨生技器材工業同業公會、中華民國醫療器材商業同業公會全國聯合會、財團法人生技醫療科技政策研究中心、財團法人工業技術研究院、財團法人資訊工業策進會

副本：衛生福利部、經濟部國際貿易局、經濟部工業局

駐德國代表處經濟組

訂

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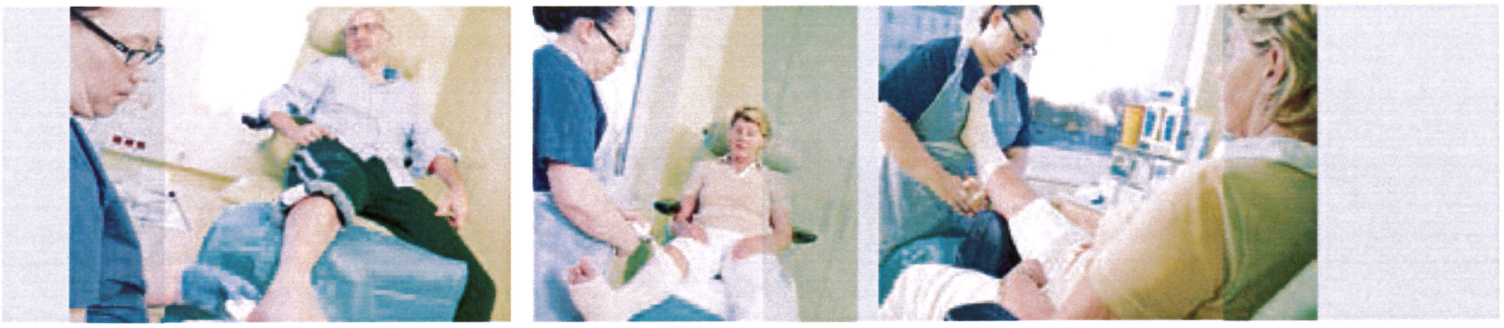
BVMed
Enhancing Health

Annual Report
2016/17

Die Unternehmen
der Medizintechnologie

www.bvmed.de



Wound care: Around 2.7 million people in Germany suffer from complex wounds, and in approximately 900,000 patients these take a chronic course. There are diverse types and locations of wounds and also many diverse products to treat them.

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Minister of Health Hermann Groehe with chairman of BVMed Dr. Meinrad Lugan

Dr. Meinrad Lugan
Chairman of the Board of BVMed

Foreword

Towards a New Culture of Innovation

Dear Members,

BVMed advocates a new and bold culture of innovation for the further development and improvement of patient care in Germany by employing technical solutions.

Modern medical technologies or telemedicine applications that focus on the needs of patients must be funded and made available to them in a timely manner. The institutions of the self-governing structure should consider it their public duty to establish a positive attitude towards medical-technical progress in society. This is the best way to provide long-term support for patients and the further development of healthcare in Germany.

All those involved in healthcare should understand that the challenges that medical care is facing—due to the rising number of older people as well as chronically ill and multi-morbid patients treated by ever fewer numbers of physicians and nurses—can only be mastered through technical advancements and innovations of treatment methods.

Therefore, in 2017, the year of the federal election, healthcare politicians together with the suppliers and care providers must provide answers to the question which types of technology will contribute to the supply of effective, efficient and dignified patient care in Germany while creating an innovation-friendly climate.

During the next legislative period a law is needed that will accelerate progress in medical care and thus introduce a culture of innovation into healthcare. This includes an improved transfer of research results into healthcare provision, the more active involvement of interest groups and patient associations in the innovation process and the meaningful inclusion of existing data on medical care. We need a critical assessment of the status quo and the acceleration of the process through which modern treatments are made available to patients.

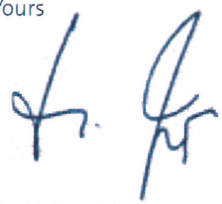
Instead of continuously demanding studies with the highest degree of evidence, and in this way using scientific processes to ward off innovations at the expense of the patients, the health insurance funds should rather cooperate with physicians, patients, and manufacturers in the development of useful care solutions, thus enabling medical-technical progress through appropriate methods for benefit assessment.

In order to preserve the innovative capacity of the medtech industry, we must adapt our remuneration and assessment systems to the dynamics of medical technologies so that patients will in future be able to benefit faster from medical progress.

A positive approach to new developments encourages understanding and implementation. This is true for medical-technological progress as well. The restoration of patients' health therefore deserves a new culture of innovation.

Together with all the partners in patient care we want to shape health, to extend high-quality care with modern medical technologies, save lives, restore mobility, and help to improve people's quality of life.

Yours



Dr. Meinrad Lugan
Chairman of the Board of BVMed

In an aging population there is increasing demand for medical technologies. Manufacturing of balloon catheters and silicone tubes, mesh implants for hernia surgery, and surgeons during 3D laparoscopy.

Market and Member Development

Member development

For the time being (March 2017) 224 industrial and trading companies are members of BVMed. In 2016, 11 companies joined BVMed. In early 2017, another 2 joined as well, while 11 companies left BVMed. There were also 2 instances of mergers or acquisitions in 2016. Despite noticeable consolidation processes and increasing pressure on margins, BVMed's number of members is still remaining stable. A complete list of members can be found on pages 22 and 23 and at *www.bvmed.de/mitglieder*.

Market development

The manufacturers of medical devices that are members of BVMed are still growing much faster through their export business than on the domestic market. The worldwide sales growth was at around 6 percent. With a sales growth rate of 4 percent, domestic development has declined slightly, according to the 2016 fall survey conducted by BVMed. Despite the difficult domestic situation, the medical technology industry in Germany continues to create jobs.

The most important results of the 2016 BVMed fall survey are:

1. The medical technology companies continue to be very successful in their export business with a growth rate of around 6 percent. With a sales growth rate of 4 percent, the development of the domestic market has declined slightly.
2. The increasing number of regulatory obstacles and slow decision-making processes in Germany as well as additional requirements resulting from the European Medical Device Regulation are a major burden especially for small and medium-sized enterprises. BVMed's innovation climate index, which has been sampled since 2011, has therefore been down slightly. The companies criticize especially the low level of remuneration in Germany. The indication areas that the BVMed companies view as particularly innovative are cardiology, oncology, and neurology.
3. What is especially relevant for the medtech companies with regard to healthcare politics is a better mutual recognition of studies within the framework of the benefit assessment of medical technologies and the faster introduction of innovations.
4. Despite the difficult domestic situation, the medical technology industry in Germany continues to create jobs. 66 percent of the companies organized in BVMed created more jobs, only 7 percent cut jobs. The job prospects for junior staff are rated "good" by 92 percent of the companies. Especially economists, engineers, and medical technicians are in demand.
5. Only 41 percent of the medtech companies say that they are currently affected by digitalization. The most significant changes they expect concern medical apps and electronic procurement processes (e-procurement).

Key industry data

- **Jobs**: The medical technology industry consists of around 1,250 businesses (considered are those with more than 20 employees in each business) that employ around 133,000 people in Germany. In addition, there are another 11,300 small businesses with almost 81,000 people. The medtech industry thus employs over 210,000 people in Germany. In addition, each medical technology job guarantees 0.75 jobs in other industries.
- **Medium-sized companies**: 93 per cent of all medical technology businesses have fewer than 250 employees. This shows that the medtech industry in Germany is predominantly still an SME industry.
- **Revenue and export**: The total revenue of the manufacturing medical technology companies (considered are those with more than 20 employees) in Germany was at over 28 billion euros in 2016, according to the official economic statistics. The export rate was at around 65 percent.
- **Growth market**: The exceptionally innovative medtech industry will continue to be a growth market due to the demographic development, medical-technological progress, and the dynamics of the emerging and developing markets. Experts estimate that the yearly growth rate will be between four and five percent.

In order to preserve the innovative capacity of the medtech industry, we must adapt our remuneration and assessment systems to the dynamics of our technologies so that patients will in future be able to benefit from medical progress without any delay.

BVMed health policy talks with Prof. Dr. Helge Braun, Minister of State in the Chancellor's Office, Karl-Josef Laumann, patient commissioner of the federal government, and Hilde Mattheis, SPD spokesperson for healthcare.

Healthcare Politics

In 2016, the coalition government continued to process the healthcare projects planned in the coalition agreement. This includes the law "Pflegestärkungsgesetz III" for the reinforcement of long-term care which contains regulatory changes with regard to medical devices. Other major changes concern hospitals, medical technical aids, and medical dressings.

Healthcare political activities

BVMed presented the specific characteristics and needs of the medical devices industry in Germany through a large number of event formats and was in close communication with the stakeholders of the healthcare sector. This included the round of health talks "Gesprächskreis Gesundheit" and several parliamentary events as well as a large number of one-on-one talks with Members of Parliament and Ministries. Basically, it can be seen that the legislative process has become increasingly detailed and based on expertise. This calls for precise analyses, a focus on the most important issues and the communication of the essential points to politicians and political institutions.

Greater involvement of industry in decision-making processes

In its communication with politicians, BVMed regularly points out that it is not only through better nursing care staff and physicians that care for patients can be improved. Nurses and physicians must be supported through technical means as well, e.g. innovations in medical technology. In Germany, we need a more positive climate for innovations. The new specialized program for medical technology "Fachprogramm Medizintechnik" developed by the Federal Ministry of Research is a step in the right direction. In addition, BVMed advocates a law that will accelerate progress in healthcare by ensuring faster transfers of research results into patient care. Important conditions for the implementation of healthcare policies are more transparency and a greater involvement of patients and the industry in the decision-making processes of the self-governing structure. This also includes granting the right to request trials for new medical technologies in the Federal Joint Committee, G-BA, to the medtech industry.

Improvements in the supply of medical technical aids

A topic BVMed considers important, but which was not part of the coalition agreement, is the reform of the provision of medical technical aids and surgical dressings to patients. The patient commissioner of the federal government received a number of complaints regarding the negative effects of tenders on the supply of medical technical aids. The government took this opportunity to improve the supply framework with a law regulating the provision of therapeutic products and medical technical aids, Heil- und Hilfsmittelversorgungsgesetz (HHVG). BVMed contributed to the discussion and the parliamentary procedure early on. In this way the association was successful in achieving improvements for patients (read more on page 8).

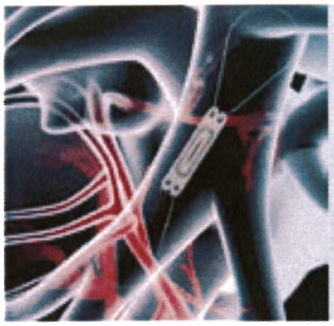
Interference with the DRG system criticized

In the hospital sector the implementation of the Hospital Structure Law passed in 2015 was of primary importance. A particularly negative aspect for the companies was the implementation of the new material costs calculation in the hospital sector by the German Institute for Hospital Reimbursement (Institut für das Entgeltsystem im Krankenhaus, InEK), which was neither appropriate nor based on data. There were incomprehensible cuts, e.g. for spine surgery or joint replacements, which will have considerable effects on the provision of care in the individual hospitals. For this reason, we reject any dirigiste interference with the DRG hospital remuneration system.

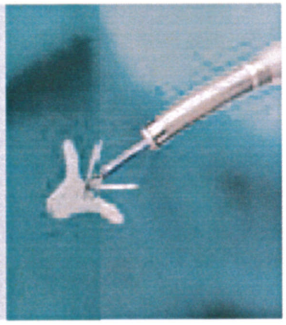
European politics

The crucial issue at a European level is the new Medical Device Regulation, MDR. In mid-2016, a political agreement was reached during the so-called "trilogue" between Council, Parliament, and Commission. The legislative process should be finished during the first half of 2017. There will be a transitional period of three years which begins when the MDR comes into force. In this respect, a large number of issues will still need clarification; delegated and implementing acts are still required. Medium-sized companies in particular fear that the new provision will lead to excessive bureaucracy and significant financial challenges.

Modern medical technologies save lives and improve people's quality of life: Spinal cord stimulation for patients with chronic pain



Implantable mini sensor that measures pressure in the pulmonary arteries



Catheter-based mitral valve replacement

Medtech Benefit Assessment and Trial Regulation

BVMed advocates separate assessment method for medical technology

The medical-technology companies accept their part in contributing towards the benefit assessment procedure—the benefit assessment of medical technologies is appropriate and important. BVMed, however, advocates a suitable way of assessing benefits that distinguishes medical devices according to different potential risks and degrees of modification.

BVMed is still advocating a neutral development of scientific guidelines for the benefit assessment of medical technologies within the framework of evidence-based medicine. These guidelines ought to better take into account the specific characteristics of the respective medical devices. The medtech companies advocate appropriate types of benefit assessment that are consistent with the highest level of patient safety. However, the primary goal must be to assure that patients in Germany will continue to quickly benefit from modern and safe medical technologies.

New assessment procedure for methods with medical devices

The assessment of new examination and treatment methods (NUB) with medical devices of higher classes (article 137 c of the Social Security Code V) involves, apart from the existing assessment procedure, a new procedure through which hospitals submit data when demanding remuneration for new examination and treatment methods for the first time. Next to the assessment of the appropriate funding for a new method by the German Institute for Hospital Reimbursement (Institut für das Entgeltsystem im Krankenhaus, InEK), the Federal Joint Committee, G-BA, will assess the benefit of the examination or treatment method.

When a hospital makes an NUB application to the InEK for the first time

- for a particularly invasive method,
- using high-class medical devices,
- that demonstrates a new theoretical and scientific concept

it is obliged to provide additional information about the application of the medical device and the latest scientific findings to the G-BA committee.

Before doing so, the hospital must consult with the manufacturer of the medical device and coordinate the NUB application and the data to be submitted. G-BA will decide about the benefit, potential or harm of the method on the basis of the data provided and the subsequent statement procedure.

The Ordinance on the Assessment of Methods with Medical Devices (Medizinproduktemethoden-Bewertungsverordnung, MeMBV) regulates the scope of application of the assessment procedure. The G-BA committee is tasked with regulating the details through its code of procedure, which the Federal Ministry of Health approved in fall 2016 only after other forms of contributing to trials than the participation in a study had been included, e.g. observational studies conducted in hospitals.

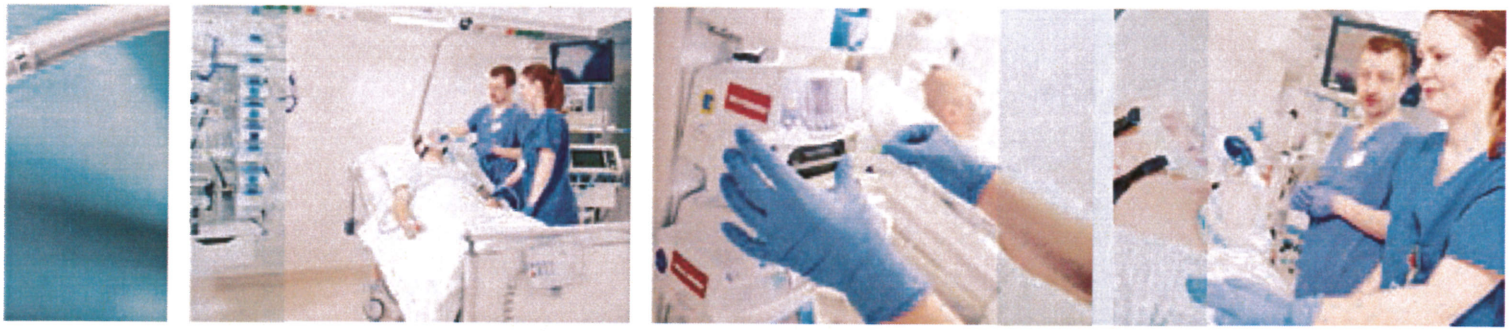
Critical issues from the point of view of BVMed

The assessment focuses on the examination and treatment methods with medical devices, not the devices as such. Only particularly invasive new procedures and methods including medical devices of higher classes that represent a new theoretical and scientific concept will be assessed.

BVMed takes a critical view of the fact that there is no mandatory involvement of the manufacturers in the procedure, as well as of the time schedules set down by the law, which will be difficult to observe. Obliging the manufacturers alone to fund the trial will be a significant burden especially for small and medium-sized enterprises and obstruct patients' fast access to innovation.

Trial regulation delays fast access to innovation

From the point of view of BVMed, the trial regulation, which was introduced over five years ago, leads to a lengthy and bureaucratic process. The procedure does not do justice to the short cycles of innovation in the medtech industry. Originally, the regulation was supposed to considerably shorten the consultation process during method assessments. This legislative objective has not been achieved. The trial regulation does not constitute a faster alternative compared to the traditional procedures for method assessments used by the G-BA committee.



Intensive care unit: The intensive care unit of a hospital provides state-of-the-art technology for the treatment of severely ill patients

Hospitals and DRGs

With the Hospital Structure Law (Krankenhausstrukturgesetz, KHSG) the government departed for the first time from the principle of the data-based calculation and assessment of case fees contained in the German DRG hospital remuneration system. The appropriate representation of medical technologies is thus no longer possible. The Hospital Structure Law contains regulations that are supposed to counteract perceived undesirable effects. By adjusting the valuation rates of material costs, by reducing or, based on the number of cases, downgrading the valuation rates as well as by making the calculation sample more representative, facts will be accomplished from the start of the 2017 DRG catalog which will have significant negative consequences for patient care with necessary innovative medical technologies.

Downgrading of procedures with high material costs

In the course of the hospital reform the DRG calculation institute InEK was supposed to analyze the excess remuneration of material costs within the DRG system and to develop suggestions for reducing these remunerations. The proposal presented by InEK assumed that the remuneration of the material costs of all case fees was generally too high without presenting the data that this assumption is based on. The proposal leads to a massive redistribution of funds for material costs towards case fees with high staff costs without taking into account the consequences of wrong incentives and undesirable effects in patient care. Increasingly, funds are being directed towards hospitals that provide lower levels of care. Highly specialized and innovative hospitals, e.g. university hospitals and centers, are losing disproportionately large amounts of funds, which will lead to declining quality in patient care.

BVMed suggests alternatives

The partners in the self-governing system have agreed to limit the initial full adjustment rate of the InEK institute, which would have reduced the valuation of the services by up to 12 percent, to half of that rate during 2017. For 2018, this will be adjusted to 60 percent. As an alternative measure, BVMed suggests a survey of cost data. The amendments should take place cautiously and over a period of several years in order to make appropriate adjustments of the valuation rates.
The calculation sample will be expanded, thus increasing the accuracy of the representation of the procedures. BVMed is in favor of maintaining the further development of the DRG system on the basis of actual data for the calculation of case fees. The unjustified cuts of the valuation rates must be reversed.

Reduction of remuneration for economically justified increases of case numbers

Another normative interference with the DRG remuneration is the intended reduction and downgrading of case fees without any justifications that are supported by empirical evidence or without any data basis. Against the legitimate resistance of the German Hospital Federation, the partners in the self-governing system have agreed to stipulate reductions and on the downgrading of the service areas of spine surgery and hip joint surgery in 2017. This will lead to reductions of the assessments by up to 6 percent, which will be accompanied by significant revenue losses. These interferences will have negative consequences for the quality of patient care and thwart the endeavor of ensuring high-quality care with medical technologies.

Quantity control through fixed cost degression

The Hospital Structure Law replaces the former discount for additional services with a new fixed-cost degression deduction, starting in the budget negotiation year 2017. The legislative objective is shifting quantity control from the federal states to the individual hospitals. In hospitals, medical devices are predominantly variable costs. The downgrading through the fixed-cost degression deduction does not affect the variable cost component. What is needed is an in-depth analysis of the DRGs that are actually affected in order to assess the fixed cost component and to ensure that the results of the negotiations are appropriate and fair. Cost-bearer invoices and process cost analyses can be used to support the assessment. The current design of the fixed-cost degression deduction carries the risk of inducing undesirable effects when services with high labor costs are to be compensated by unjustified reductions in material costs.

Care with medical technical aids: Wound care, incontinence care, artificial nourishment, and ostomy care

Medical Technical Aids and Wound Dressings

BVMed has been drawing attention to various undesirable developments in the area of medical technical aids, addressing politicians with demands and proposals for solutions. The government recognized the need for action already in 2015 and initiated an amendment of the law in order to assure the quality of the supply of medical technical aids, which was passed in spring 2017.

HHVG and medical technical aids

The Law Regulating the Provision of Therapeutic Products and Medical Technical Aids (Heil- und Hilfsmittelversorgungsgesetz, HHVG), addresses the major challenges articulated by BVMed to eliminate the supply deficits that were found, e. g.:

- introduction of quality for the award of tenders;
- stricter monitoring of the implementation of contracts by means of sampling and abnormality tests;
- update of the register of medical technical aids;
- introduction of uniform service criteria throughout the country;
- obligation for the health insurance funds to inform their insured about the major contract details;
- obligation for the care-providers to provide details about the amount of additional payments for economic reasons during the settlement procedure according to article 302 of the Social Security Code V;
- legal clarification that only the Medical Review Board of the Statutory Health Insurance Funds (Medizinischer Dienst der Krankenkassen, MDK), but not the health insurance funds themselves, may engage third-party consultants for medical technical aids;
- clarification of the distinction between innovative medical technical aids and new examination and treatment methods (NUB).

The HHVG law provides for the introduction of a code of procedure during the update of the register of medical technical aids as well as for a guideline recommendation to implement contract controlling. BVMed's professional experts are developing precise suggestions to implement these measures, which will serve as a basis for discussion.

Further need for legal regulations

After the reform is before the reform—in order to ensure quality-assured and individual patient care in the medium and long term BVMed advocates further legal amendments. These should include:

- banning tenders for medical technical aids with a high level of service, such as homecare therapies;
- the active and mandatory participation of the relevant umbrella organizations of the federal associations of the care-providers and manufacturers, including the update of the register of medical technical aids and the design of the code of procedure;
- binding, transparent, and nationwide regulations for contract controlling.

HHVG and wound dressings

With the HHVG law, the government has introduced a legal definition of wound dressings alongside the regulations for therapeutic products and medical technical aids. The definition is designed to create legal certainty for the prescription of wound dressings. It is supposed to cover all "conventional" types of dressings so that these will be remunerated directly by the health insurance funds without any restrictions or additional assessment procedure. With regard to new types of medical devices that are "similar to dressings", there will be an assessment procedure performed by the Federal Joint Committee, G-BA, in order to prove the necessity and benefit of use. Only after it passes this procedure successfully, will the device be remunerated by the health insurance funds.

The government has decided on a definition of "conventional" dressings that also includes dressings with additional benefits, thus accepting the arguments of the medical societies and BVMed. In this way, the phase-specific treatment of chronic wounds will be ensured in the future, too.

Implementation of the HHVG law with regard to dressings

It is now up to G-BA to develop a regulation that will define the difference between "conventional dressings" and "medical devices that are similar to dressings". BVMed will play an active role in this process and draw up stringent suggestions for the design of the regulation and the subsequent assessment procedure.

Homecare: Homecare companies care for patients with medical technical aids, enteral nutrition, and surgical dressings—at home and in nursing homes.

Homecare

In 2016, the trend towards lower prices in many areas of medical technical aids continued. Contract negotiations still all too often focus on prices rather than on the quality of care. Tenders play an important role in this respect, even though it is well known that this instrument has led to a loss of quality and distortions in the provision of medical technical aids. Health insurance funds have used this contract option even for critical areas where tenders are not useful, e.g. medical technical aids with a high level of service, such as ostomy, draining incontinence help, and decubitus care.

Homecare tenders jeopardize patient care

BVMed believes that patient care in homecare therapy areas is severely jeopardized by tenders. These have resulted in massive losses of product and service quality in homecare as well as restricted the patients' freedom to choose their service provider and preferred medical technical aid. In order to receive the required level of care patients are often forced to make additional payments. The principle of benefits in kind is thus undermined to the detriment of the patient.
In order to secure the supply of homecare, BVMed considers it absolutely necessary to maintain the unrestricted freedom of choice of the patients with regard to the device / service and the care-provider. BVMed and its quality of life initiative "Faktor Lebensqualität" (*www.faktor-lebensqualitaet.de*) therefore support a ban on tenders in these areas of care—negotiated contracts according to article 127, section 2 of the Social Security Code V must be the primary option!

Legal basis for homecare

Homecare means that patients at home and in nursing and retirement homes receive medical technical aids, wound dressings, or medical nutrition together with any relevant services by specialist care providers. Through the HHVG law the government has also expanded the entitlement of patients to use the service that is part of the medical technical aid. In addition, the Federal Association of the Statutory Health Insurance Funds, GKV-Spitzenverband, has been obliged to define the minimum requirements for the service to be provided and to include these in the register of medical technical aids. In this way, BVMed has been successful in making homecare part of social law.

Awareness for homecare

BVMed aims to improve awareness for the role of homecare and the importance of homecare companies within the care process. More than 150 representatives of the providers of homecare and medical technical aids as well as health insurance funds, physicians, and hospitals took part in the third Homecare Management Congress 2016, where they discussed the requirements for high-quality supply of medical technical aids and the challenges of successful networked care. Further elements to strengthen its role as the main contact point for homecare are the BVMed Medical Aid Forum at the Rehacare fair and the periodic homecare newsletter.

Digitalization

The E-Health Law, which came into force in 2016, stipulates binding deadlines for the introduction of the digital medication plan and the digital patient file.
At present, the government has not yet announced any details on how the other care-providers are to be involved. BVMed is continuing to work for the timely and non-discriminatory integration of all care providers.
To this end, it is in close contact with the relevant stakeholders and actively contributes to the advisory council of the Electronic Register of Healthcare Professions (elektronisches Gesundheitsberuferegister, eGBR). BVMed also aims to ensure that the entire care process is documented in digital form. In order to achieve this, further digital applications must be introduced. BVMed therefore calls on the political decision-makers to create the necessary framework, e.g. for the introduction of nationwide electronic prescriptions.

European Court of Justice confirms framework agreements

In June 2016 the European Court of Justice confirmed the privilege to award so-called open-house contracts. The decision also supports the framework agreements with the ability to join according to article 127, section 2, 2 a of the Social Security Code V. Apart from that it finally creates legal certainty and strengthens the position of framework agreements as opposed to tender contracts.

Education, research, manufacturing, and quality assurance in medtech companies focus on one goal: helping patients.

Medical Devices Law

European Medical Device Regulation

Almost five years after the announcement of the two Commission proposals for the European Medical Device Regulation (MDR) and the European In Vitro Diagnostic Medical Device Regulation (IVDR) of September 2012 they are due to be adopted truly soon in mid-2017.
The regulations will come into force in 2017 and their application will become mandatory three years later. Up to that point in time (mid-2020), old certificates that have already been issued will remain valid for another five years (MDR) or two years (IVDR). At present, it is still unclear to what extent the new law will have to be applied in every case after the application date (in mid-2020). This uncertainty concerns e.g. the notification obligation and market surveillance.
The new EU regulatory framework will not lead to easier market launches of medical devices in the internal EU market, as initially envisaged by the Commission, but will in fact further complicate this process. Compared to the former directive MDD, for instance, the MDR contains more than 100 additional articles. Instead of 12 annexes, as before, the MDR will contain 16 annexes. In addition, it is to be extended by 32 new implementing and another 11 delegating acts that will yet have to be developed.

Major changes brought about by the MDR:

- Introduction of the so-called scrutiny procedure for class III implants and class IIb devices for the application or removal of medical drugs.
- New regulation of market surveillance with shorter reporting deadlines.
- Additional reports and plans: Post Market Surveillance Plan / Report (PMS), Post Market Clinical Follow-up Report (PMCF), Periodic Safety Update Report (PSUR), Summary of Safety and Clinical Performance (SSCP).
- Significantly stricter requirements for the preparation of clinical data, e.g. during clinical evaluations: equivalence consideration made more difficult; reference to raw data for comparison subject to competitor's consent; stricter demands made on the clinical evaluator; clinical tests will become mandatory for implants and class III devices.
- Staged introduction of UDI code.
- Higher classification of certain substances and surgically invasive medical devices.
- Extension of the application area to include certain instruments for cosmetic surgery.

Notified Bodies

Due to the change in the legal framework, all Notified Bodies in Europe will lose their notification. Applications for renotification can be made six months after the MDR and IVDR have come into force at the earliest. It is completely unclear in what order the medical technology companies will be certified after the renotification of the Notified Bodies and how their upcoming need for new expert staff can be met.

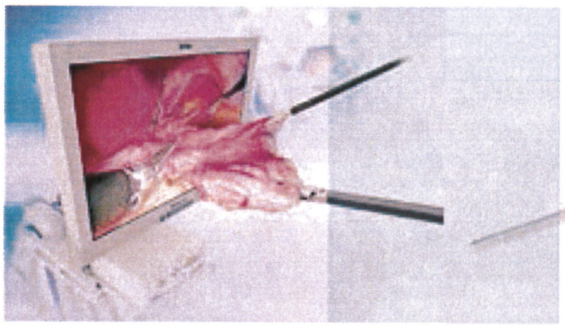
SMEs particularly affected

Especially small and medium-sized enterprises, SMEs, are concerned that their certification might be deferred because of their lower buying power. Given their smaller numbers of staff and funding opportunities, it is likely that small and medium-sized enterprises will also be particularly hard hit by the extensive clinical requirements as well as documentation and reporting requirements. What is urgently necessary therefore is a nationwide funding program for these smaller SMEs in order to ensure their existence.

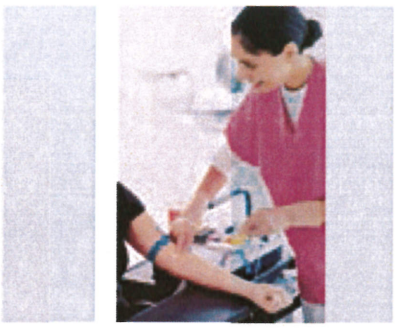
National law

In 2016 and early 2017, a large number of amendments of national law have come into effect. These concern the following laws: Medical Devices Law (Medizinproduktegesetz, MPG), Medical Devices Ordinance (Medizinprodukteverordnung, MPV), Medical Devices Operator Ordinance (Medizinprodukte-Betreiberverordnung, MPBetreibV), Medical Devices Safety Plan Ordinance (Medizinprodukte-Sicherheitsplanverordnung, MPSV), Medical Devices Supply Ordinance (Medizinprodukte-Abgabeverordnung, MPAV), Medical Devices Fee Ordinance (Medizinprodukte-Gebührenverordnung, MPGebV), Accreditation Body Act (Akkreditierungsstellengesetz, AkkStelleG), Accreditation Body Cost Ordinance (Kostenverordnung der Akkreditierungsstelle, AkkStelleKostV).

Port system for infusion therapies in hospitals



Modern working premises: 3D laparoscopy



Safety devices to avoid needlestick injuries

Patients, Occupational and Environmental Safety

Hygiene and medical devices

In 2011, the Infection Protection Law (Infektionsschutzgesetz) was amended in order to reduce the number of hospital infections. The amendment of the law introduced measures for the correct use of diagnostic instruments and the ambulatory therapy of patients who are infected with the multiresistant MRSA pathogen. Even though fewer MRSA infections are registered, multiresistant pathogens will remain a general problem. BVMed has positioned itself with regard to hygiene especially through its information initiative about healthcare-associated infections.
Its website *www.krankenhausinfektionen.info* offers all those interested, especially teachers and students of hygiene and care, high-quality graphics about the major modes of transmission in medical institutions and how to avoid the spread of infections. Currently, a short video clip explains nosocomial infections. In the reporting year new graphics will be added that visualize the development and spread of multiresistant pathogens.

Reprocessing of medical devices

A possible cause of infection in medical institutions is the reuse of medical devices if these are reprocessed improperly or if the device is not suitable for reuse. The EU Medical Device Regulation, MDR, will create new conditions for both cases. It will include an article on single-use devices and their reprocessing that will regard reprocessors of single-use devices as their manufacturers. At the same time, it will enable the member states to provide exceptions for medical institutions and their reprocessors. With regard to reusable class I devices the questions of reusability, including the operating instructions, are to be reviewed through the audit conducted by a Notified Body. BVMed calls for common standards in safeguarding patient protection.

Employee and nursing staff protection: sharps injuries and contaminated returns

Also employees of medical institutions are exposed to a particular risk of infection. There are potential dangers for nurses and physicians, but also cleaning and waste disposal staff, when they handle potentially contaminated materials, such as syringes or medical devices returns. In order to avoid "needlestick injuries", i. e. injuries from sharp medical instruments, the use of safety devices is mandatory when there is a risk of infection. However, there are still shortcomings in the implementation in ambulatory care. With regard to safety devices used in physicians' surgeries, care homes or at home, the remuneration by the health insurance funds is not ensured in a consistent way. BVMed calls for a uniform interpretation of the safety provisions by the health insurance funds and is working towards raising awareness of the shortcomings among those responsible for health and safety at work.
BVMed has made available to all those concerned a comprehensive information package that deals with the protection of employees who handle potentially contaminated medical devices returns (*www.bvmed.de/retouren*).

Environmental protection in the medtech industry

Bans, restrictions and reporting requirements in connection with substances as well as special requirements for placing substances on the market remain the predominant environmental issue within BVMed. In the course of the EU chemicals regulation REACH the duties with regard to substances are updated continuously. In early 2017, 173 "Substances of Very High Concern" are listed that require registration and with regard to which the manufacturers must inform their customers immediately if they are present in any products. A particular challenge for the manufacturers, apart from the research, documentation, and information effort, is the search for alternatives in case a substance is not granted registration or is subject to restrictions. In future, the medical devices law will add new requirements. The EU Medical Device Regulation, MDR, provides for comprehensive rules for substances and labeling obligations for all those medical devices that touch the human body and contain more than 0,1 % by weight of substances identified as dangerous. BVMed has advocated a risk management system with regard to the regulations of substances that will provide a reasonable balance between environmental protection and maintaining high-quality medical care.

17th BVMed Media Seminar on the situation of the medtech industry and the results of the BVMed fall survey

Communications and Media Projects

Storytelling and patients' stories

The medical technology companies must tell more emotional and authentic stories that illustrate how their devices and care solutions support patients and improve their quality of life. In this way, the importance of the medtech industry for healthcare can be communicated more effectively. This insight was the core message of the 2016 Medtech Communication Conference and will be discussed in more detail at the next conference to be held in June 2017.

After all: Technical devices like medical technologies have great potential for emotional stories as well, especially since they save lives, improve people's quality of life and offer surprising variations during product development and application. Companies must understand that the real story is the person using medical technologies, and the device is the "hidden hero".

The use of videos that support the message and the early involvement of patient support groups help spread the patient stories widely via social networks and print and online media. In this age of digitalization and social media the employees of medical technology companies are becoming increasingly important as ambassadors to reach the public.

Information campaign "Der Mensch als Maßstab"

Providing information about the importance and value of medical technologies is an important task of BVMed: for the public, for healthcare, for the economy in general. A core element of BVMed's public relations activities is the information campaign "Der Mensch als Maßstab. Medizintechnologie"—Measuring by the Human Standard. Medical Technology—(*www.massstab-mensch.de*), which was started in 2010. With its sophisticated aesthetics, large posters, and unusual magazines the campaign is breaking new ground in the medtech industry.

Patients showing "Body Pride"

The campaign continued in 2015 with a new series of themes called "Körperstolz" (Body Pride, *www.bvmed.de/koerperstolz*). They portray patients with chronic diseases who live their lives to the fullest. The campaign focuses on six motifs—ostomy, incontinence, artificial nourishment, diabetes, tracheotomy / laryngectomy, and dialysis—as well as in-depth interviews with patients and video clips. In 2017, the care areas of lymphedema after breast cancer, implanted defibrillator (ICD) applying telecardiology, and shoulder prosthesis will be added. The campaign aims to improve the public's understanding of the situations the patients face in their lives, and to show the importance of medical devices for a self-determined life. The motto is: "Every human being is unique. We help some of them to live like everybody else."

Patient information

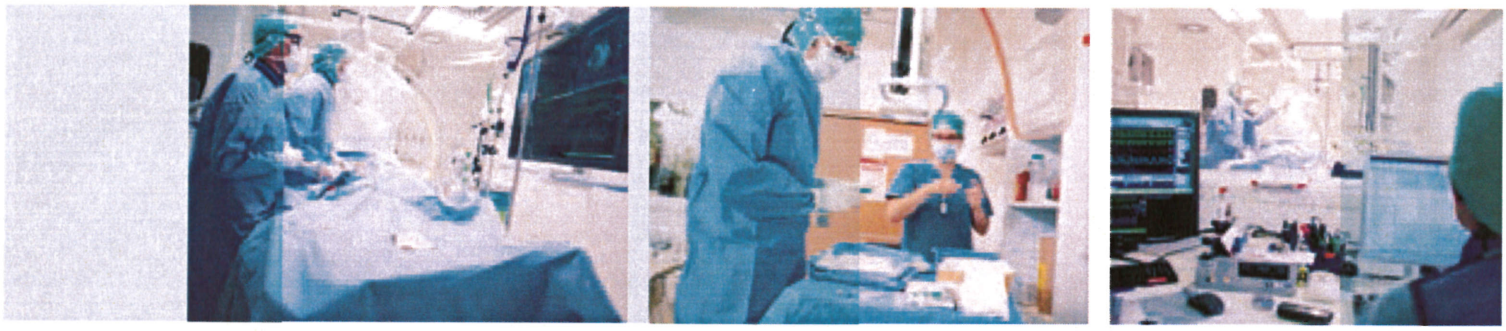
Medical-technological progress, an aging population, and new information technologies: comprehensible and up-to-date patient information is becoming more and more important against this background. BVMed has accepted this challenge with "Aktion Meditech" (*www.aktion-meditech.de*)—always working closely together with physicians and patient groups. BVMed's website (*www.bvmed.de*) also offers clearly structured information about medical-technological solutions for various diseases, as well as patient information films.

Media activities

BVMed is continuously addressing and working with the media. Thus, BVMed was able to assure that over 4,100 articles mentioned the association in various print and online publications in 2016, reaching over 105 million readers. The weekly BVMed newsletter with more than 8,000 subscribers remains an important feature of the medtech industry. The other areas of media work are our own photo galleries, "BVMed Bilderwelten", press conferences, the annual Media Seminar, as well as press releases, background services, guest articles, and industry reports in German and English.

Social media and medical technology

Social networks have become an important element of the communication activities of the medical technology industry. BVMed makes use of the opportunities that social networks offer, e. g. via its own Twitter channel (*www.twitter.com/bvmed*) with more than 2,000 followers as well as several Facebook pages displaying technological and career topics.



Catheter laboratory: Treating vascular occlusions with state-of-the-art medical technology.
A cardiologist inserts a guiding catheter via the groin to the narrowed section and expands it.

Reports from the BVMed Expert Committees

BVMed offers its members over 60 working groups, sectoral interest groups, and project groups, which function as a platform for constructive dialog and exchange, leading to a joint formation of opinions.

Working groups deal with issues of general concern to all members on a continuous basis, irrespective of their particular products.

Sectoral interest groups consist of members working in a specific market or product area, who wish for additional representation of their particular specialist interests.

Project groups are committees set up on a temporary basis. They deal with a specific subject and provide expert support to the board of BVMed and the management team in this particular field.

A complete list of BVMed's groups can be found at: *www.bvmed.de/arbeitsgremien*.

WORKING GROUPS

Working group "Environment, Health and Safety" (AKEHS)

AKEHS is the successor of the former environmental working group. The change of name does justice to the fact that environmental protection and health and safety at work are connected in many ways and reflects the achievement of the most active project group, PG "Occupational health and safety for employees of medical-technology companies". It focuses on protection measures for field staff working in distribution, service, and application support who are thus exposed to a higher risk of infection. The project group has presented a comprehensive information package that deals with handling medical devices returns. The project group "Product properties, design" is concerned with the comprehensive and continuously growing legal provisions, proposed bans and restrictions regarding the use of substances. It works towards a more appropriate assessment of medical and environmental goals. The focus of the project group on recycling management is on developing the Packaging Ordinance into a Packaging Act.

Working group "eStandards" (AKE)

AKE is the representation of the BVMed members in the "Forum eStandards". The forum consists of representatives of hospital purchasing groups and BVMed member companies, and has established itself as a platform for the joint development and dissemination of recommendations for electronic communication in the exchange of business data. The basis are the papers published by the forum, which recommend a standardized approach to implementing product classification, master data exchange, electronic data interchange, and electronic invoicing. A new feature is the forum paper "Sales Report". Through this report the suppliers submit their revenues from the relevant member or contractual hospitals to the purchasing groups. The agreed common content and a small number of formats should significantly reduce the relevant workload for all those involved. Another focus of AKE is on the concept of UDI (Unique Device Identification), which will be introduced with the European Medical Device Regulation.

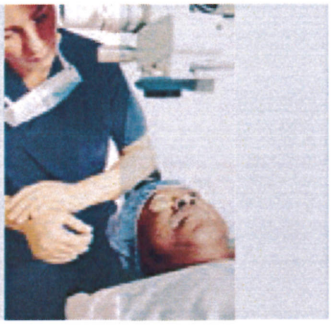
Working group "Hospital Market" (AK KHM)

AK KHM is the contact point for industry-specific questions with regard to hospitals during the buying process. It provides a communication platform where joint projects and activities concerning the buying process of medical technologies in the hospital market can be developed. This includes legal matters, e.g. with regard to the rules for submitting tenders. Together with the relevant purchasing organizations it discusses market requirements and process optimization during the buying process. Another focus is on the logistic processes between the companies, service providers, and hospitals. In addition, AK KHM cooperates closely with AKE, e.g. on the development and design of the recommendation on sales reports, i.e. the electronic transfer of sales data.

Working group "Legal Affairs" (AKR)

The members of AKR—in-house legal advisers—and the external lawyers of the associated "Network Medical Devices Law" answer questions concerning legal matters from the BVMed working committees. To this end, AKR has formed 16 sub-working and project groups. AKR mostly deals with medical devices law, compliance, product liability, and data protection on a national and

Eye surgery: Modern procedures for defective vision and cataract



Cataract surgery

European level. AKR provides member companies with legal assistance via guidelines, journal articles, and events. The members and the network of AKR also update the BVMed loose-leaf commentary on the Medical Devices Law "WiKo—Medizinprodukterecht", which will be published in the second quarter of 2017 in its 16th edition. The commentary is accompanied by a blog (*www.wiko-mpg.de*), which is updated regularly. The blog is an online law database, which currently lists over 430 court decisions about medical devices. Last year, the blog was complemented by an electronic newsletter (*www.gesr.de/wiko-newsletter.htm*), which provides comments on the latest court decisions listed in the blog.

Working group "Regulatory and Public Affairs" (AKRP)

The priority issue in 2016 was the legislative process for the introduction of an EU Medical Device Regulation. AKRP fears there will be a bottleneck during the transition from the old to the new law in 2020 and therefore demands the suitable and appropriate handling of the transition and sell-off period by the competent authorities. Any overregulation caused by a very narrow interpretation of the new provisions should be avoided especially during the initial phase. AKRP cooperates closely with national and European expert groups (DIN German Institute for Standardization, Germany's national accreditation body DAkkS, the Federal Ministry of Health, the authorities of the federal states, the ZLG (central authority of the federal states for health protection with regard to medicinal products and medical devices), the Notified Bodies, the Federal Institute for Drugs and Medical Devices, the German Institute of Medical Documentation and Information, the European Commission, MedTech Europe, the European Committee for Standardization (CEN), and ISO). Within the national Medical Devices Law Working-Group of the Associations of the Medtech Industry (Arbeitsgruppe MPG der Industriefachverbände, AG MPG) AKRP develops regulatory statements and information flyers and hosts events. AKRP also answers questions concerning regulatory matters from the BVMed working committees. To this end, AKRP has formed eleven sub-working and project groups. In addition, AKRP is in charge of editing the BVMed information sequence "Medizinprodukterecht" (Medical Devices Law), which currently consists of eleven guidelines on different regulatory and legal matters.

Healthcare Compliance Committee (HCCC)

The key issue in 2016 was the Anti-bribery Act in Healthcare passed in mid-2016. The law implemented a decision by the Federal Court of Justice with regard to the criminal offense of bribery, which did not apply to practice-based statutory health insurance physicians before. The legislative process amended wordings which were too vague and would have undermined cooperation models desired by social law. This has resulted in a good compromise that will ensure the politically desired cooperation between physicians, medical institutions, and the industry in the interest of developing innovations and improving appropriate patient care can take place in future as well. We provide information about the new regulations to companies and medical institutions with the help of our campaign "Medtech Kompass", training seminars, learning programs, and model contracts (*www.bvmed.de/compliance*).

BVMed Medium-sized Company Forum

In view of the growing burden of regulatory requirements the BVMed forum for medium-sized companies, "BVMed-Mittelstandsforum", was formed in 2016. The forum considers itself as the representation body especially of smaller companies, which, according to a definition by the European Union are those with fewer than 50 employees. Together with the medium-sized companies, i. e. those with fewer than 250 employees, the SME account for more than 90 percent of all members of BVMed. The reason for creating the forum is the EU Medical Device Regulation, MDR, which is expected to come into force in mid-2017. The documentation and reporting requirements will bind substantial staff resources that the small companies will hardly be able to provide on their own. In addition, the small companies fear that due to their small size their certification might be deferred by the Notified Bodies, possibly until after the mandatory application date of the MDR. During their second SME forum held in January 2017 the small companies decided to maintain the forum in order to

Diabetes: Insulin pumps and continuous glucose monitoring for children with diabetes

Endoprosthetics: Doctor-patient talk about hip and knee joint replacements

continue their exchange and positioning on regulatory matters.

SECTORAL INTEREST GROUPS

Sectoral interest group "Eye Surgery" (FBA)

FBA represents the manufacturers and distributors of medical devices used in surgery on or in the eye, especially intraocular lenses, IOL. FBA bases its campaign "Cataract Initiative" (*www.initiativegrauerstar.de*) about the additional benefits of innovative intraocular lenses on the further development and patient-friendly design of its web presence. FBA calls for appropriate and uniform quality requirements for IOL on the basis of international standards.

Decubitus Forum (DF)

The focus of DF was on public relations work and the revision of product group 11 (devices for the prevention of decubitus) of the register of medical technical aids. Apart from that the sectoral interest group aims to create the framework conditions to ensure patient-oriented care with anti-decubitus medical technical aids. To this end, a number of roundtable discussions between manufacturers and the relevant care-providers took place. As a first step, the forum has established and agreed the process steps required in connection with anti-decubitus care in order to define the framework conditions that are needed to ensure patient-oriented care and to embed them in the market. In addition, a joint position paper on how to improve decubitus care was developed. The website *www.dekubitus-forum.de* complements the public relations activities of the Decubitus Forum.

Sectoral interest group "Diabetes" (FBD)

FBD aims to ensure that innovative diabetes technologies and therapies are available to all those who need them on a timely basis. Thus, FBD regards itself as a competent point of contact with regard to diabetes technologies. The focus of its activities are active press and public relations work.

Sectoral interest group "Diagnosis Related Groups— Hospital Financing" (FB DRG)

FB DRG accompanies the further development of the G-DRG hospital remuneration system, focusing especially on the appropriate representation of medical technologies. FB DRG coordinates the suggestions made for the further development of the DRG and OPS classification within BVMed. FB DRG also draws up statements on legislative processes and has prepared a guideline on the remuneration of material costs within the 2017 DRG catalog. It is in dialog with the hospital federations, the health insurance funds and the hospital market associations.

Sectoral interest group "Endoprosthetics—Implants" (FBEI)

The White Paper on Joint Replacements, which was published by the healthcare research institute IGES in 2016, has been received with great interest by politicians as well as experts. It presents the significance and treatment opportunities as well as the scientific data on hip and knee joint replacements in Germany and provides accompanying expert opinions. The white paper proves that with regard to joint replacements, we have achieved a high level of patient satisfaction and treatment quality in Germany. The Endoprostheses Register Germany, EPRD, is another success story. The register was jointly launched by physicians, hospitals, health insurance funds, and the industry. Collecting, in line with data-protection requirements, surgery data about the implantation of artificial hip and knee joints in hospitals and linking these with routine data generates information about the quality of the implants and the medical treatment. At the end of 2016, more than 730 hospitals had registered for participation in the EPRD. In total, over 446,000 operations have already been recorded.

Sectoral interest group "First-Aid Material" (FBEH)

FBEH is the interest group of the manufacturers of first-aid materials and kits, which are used for cars, motorcycles, and businesses. Its members campaign for the continuous adjustment of first-aid materials according

Cardiology: Cardiac pacemaker, implantable defibrillators, and telecardiology monitoring of patients with pacemakers

to the latest findings of modern emergency and disaster medicine. FBEH and the working group "Communication", AGK, of the manufacturers of first-aid kits for motor vehicles provide information about the importance and benefits of first-aid kits and about the duties of the users through their continuous press work.

Sectoral interest group "Homecare" (FBHC)

FBHC analyzes the developments with regard to tenders and accompanied the reform of the medical technical aids law, HHVG, by publishing statements and holding events. FBHC also aims to raise awareness for homecare and to stress and strengthen the importance and role of homecare in ambulatory care. To this end, BVMed hosted the third Homecare Management Congress in 2016; FBHC played a prominent role in organizing the congress. A regular homecare newsletter for decision-makers and public relations work through the website *www.perspektive-homecare.de* accompany its activities.

Sectoral interest group "Cardiac Medical Devices" (FBKMP)

FBKMP is concerned with medical technologies that are used in cardiovascular treatments and examinations. Working groups and projects within the sectoral interest group exist for active implants (cardiac pacemakers, ICD-CRT systems, telecardiology), interventional technologies (stents), as well as interventions through heart surgery, such as prosthetic heart valve technologies, cardiopulmonary systems, or artificial heart technologies. An exhibitors' advisory council is in dialog with the medical societies and professional associations in terms of congress and further training activities.

Sectoral interest group "Artificial Nourishment" (FBKE)

FBKE campaigns for the medically necessary, sufficient, and appropriate supply and reimbursement of medical enteral nutrition. It contributed to the commenting procedure of the G-BA committee on the amendment of the prescription guideline "Arzneimittelrichtlinie" in the focus area of balanced diets for enteral nutrition ("Bilanzierte Diäten zur enteralen Ernährung"). In addition, FKBE is developing a suggestion for the restructuring of product group 03 of the register of medical technical aids as well as minimum requirements for services in this area of care. In this way, adequate quality requirements for the supply of medical aids in terms of the application of enteral and tube feed nutrition are to be defined during the forthcoming update of the register of medical technical aids. FBKE is in close contact with the "Diätverband", the association of the manufacturers of food for special dietary use.

Sectoral interest group "Health Insurance Law for Service Providers" (FBLL)

FBLL supports BVMed in drawing up statements and analyzing legislative proposals and court decisions with regard to social and procurement law. In 2016, its focus was on the law regulating the provision of therapeutic devices and medical technical aids, HHVG. Furthermore, the sectoral interest group was preoccupied with the amendments of the anti-corruption law, the reform of the procurement law, and the care reinforcement law with a focus on hospital discharge management.

Sectoral interest group "Market Access" (FBMA)

FBMA combines the activities for the timely market launch of innovative medical devices and their representation in the service catalogs. This involves adequate reimbursement levels and overcoming access barriers to remuneration and refunding. Other focal topics of FBMA are benefit assessment and healthcare research. It discusses methodological approaches to benefit assessment schemes of medical technologies and comments on the procedural rules and processes of the new evaluation of methods of medical devices. In order to provide assistance to the medtech companies, FBMA developed guidelines on the practical application of the benefit assessment procedures.

Sectoral interest group "Mechanical Thrombosis Prophylaxis" (FBMT)

FBMT is concerned with all matters of physical thrombosis prophylaxis. Its focus is on public relations work and on regular dialogs with physicians and nursing staff. This exchange is aimed at maintaining the care situation in the area of thrombosis prophylaxis in the medium- and long-term.

E-Health: Blood sugar measurement and doctor consultation via iPhone app

Sectoral interest group "Modern Wound Care" (FBMW)

The focus of FBMW was on the legal definition of wound dressings (article 31 of the Social Security Code V) as part of the HHVG law. In its comment on the latter the sectoral interest group demands that the phase-specific treatment of chronic wounds will be ensured. In addition, FBMW continued its public relations work (*www.info-wundversorgung.de*). With the second wound dialog on the issue of a better framework for wound care, "Wundversorgung braucht bessere Rahmenbedingungen", the sectoral interest group has also created a platform for discussing and advancing joint solutions for the improvement of the current situation of wound care in Germany with all those concerned. A separate sub-working group has developed best practice guidelines for the local antimicrobial treatment of wounds. The results were presented at the German Wound Congress of ICW—Initiative on Chronic Wounds—in May 2016.

Sectoral interest group "Needlestick Prevention" (FBNSP)

FBNSP is the interest group of the manufacturers of safety devices for the prevention of sharps injuries. According to the Technical Rule for Biological Agents TRBA 250 "Biological Agents in Healthcare and Welfare Facilities" safety devices must be used if there is a risk of infection. In ambulatory care, especially when patients are cared for at home or in care homes, there are still deficits in remuneration by the health insurance funds. The sectoral interest group advocates a uniformly high protection level for all those who are at risk of sharp injuries, skilled professionals, as well as private caregivers.

Sectoral interest group "Renal Replacement Therapy" (FBNE)

The members of FBNE are the suppliers of dialysis technology devices. FBNE aims to inform the public about the importance of these life-saving medical technologies and the conditions necessary to make them available.

Sectoral interest group "Nosocomial Infections" (FBNI)

Despite their different ranges of products, the active members of FBNI are united by one common ambition: the prevention of hospital infections. They contribute to this goal through their own website "Infektionen vermeiden—bewusst handeln" ("Avoiding Infections—Acting Sensibly" at *www.krankenhausinfektionen.info*) and the "Hygiene Forum" of BVMed, which takes place once a year and addresses the employees of medical institutions and representatives of the self-governing bodies and politics. On its website, FBNI visualizes the most common ways of infection and describes how infections can be prevented. In 2016, a video clip explaining hospital infections complemented the information offered. In the reporting year, the sectoral interest group is focusing specifically on multi-resistant germs and how to prevent them.

Sectoral interest group "Peripheral Vascular Medicine" (FBPG)

FBPG is concerned with medical technologies used in the peripheral circulatory system, e. g. PTA technologies, drug-coated stents, stent grafts and intercranial systems for stroke therapy. The activities at specialist congresses are coordinated together with the professional medical societies through an exhibitors' advisory council. Another task is the coordination of register projects.

Sectoral interest group "Rehabilitation Technology Supply for the Preservation of Mobility and Care" (FB Reha)

Mobility and rehabilitation technology care aids are the basis of providing ambulatory care. The newly established sectoral interest group FB Reha aims to create the necessary framework for the supply of these medical technical aids. This includes the definition of minimum requirements for structural and process quality in these areas of care. FB Reha has, for instance, developed a proposal for the qualification of technical managers in rehabilitation institutions.

Caring for premature babies: Medical care for premature babies has constantly improved over the last 30 years thanks to the progress of medical technology.

Sectoral interest group "Absorbing Incontinence Care—Manufacturers" (FBI-H)

FBI-H plays a significant role in taking a critical look at the care and contract situation for absorbing incontinence products. It aims to assure patient-oriented and medically necessary care in the long term. To this end, FBI-H invited representatives of the health insurance funds to take part in a roundtable discussion about the effects of the update of the product group 15 of the register of medical technical aids to reflect the current contracts.

Sectoral interest group "Soft Tissue Repair Implants—Soft Tissue" (FB STRI)

FB STRI represents the interests of the suppliers of implants for soft tissue reinforcement. The sectoral interest group's aim is the discussion of the joint interests and needs for this type of product as well as the coordination of the resulting activities, e.g. regarding reimbursement and aspects of quality. The group works especially on the therapy areas visceral surgery, gynecology, and urology, as well as plastic surgery. In the context of health services research, the sectoral interest group accompanies the register project dealing with hernia and biological implants, Herniamed.

Sectoral interest group "Spine Surgery" (FBSC)

FBSC supports the establishment and appropriate representation of medical technologies for the spine within the classification and remuneration catalogs, as well as the development of instruments for health services research. In cooperation with the German Spine Society (Deutsche Gesellschaft für Wirbelsäulenchirurgie, DWG), FBSC is involved in the development and design of the German spine register. Together with the professional societies it coordinates congress activities.

Sectoral interest group "Sterile Materials Care" (FBSV)

FBSV is concerned with the exchange on issues concerning the requirements of sterile products and devices that must be used in a low-germ environment. Specific topics are dealt with in the sub-working groups "Ethylene Oxide Sterilization" (AGEO) and "Radiosterilization" (AGS).

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

FBSI focuses on the topic of quality-assurance in ostomy and draining incontinence help care. It analyzed the update of product group 15 of the register of medical technical aids in March 2016 as well as the current reform of the medical technical aids law, HHVG. During a press conference, FBSI opposed tenders and advocated individual care for patients in the homecare therapy areas of draining incontinence and ostomy care.

Sectoral interest group "Therapeutic Apheresis" (FBTA)

The members of FBTA are companies that offer technologies for extracorporeal blood cleansing. The member companies support the German Lipidapheresis Register (Deutsches Lipidapherese-Register, DLAR), which will compile a systematic documentation of lipidapheresis procedures. In the reporting year it was decided to continue the support of the register until 2019. The DLAR register aims to substantiate known positive results with the help of a wide range of data, thus securing established forms of therapy.

Sectoral interest group "Tracheotomy / Laryngectomy" (FBTL)

In cooperation with the society of ENT specialists and the relevant professional association, FBTL was able to initiate a survey among physicians about the quality of care. Another topic was the update of the register of medical technical aids. The sectoral interest group has already submitted initial solution approaches to the Federal Association of the Statutory Health Insurance Funds (GKV-Spitzenverband). In addition, a project group within FBTL has updated the BVMed brochure "Empfehlung für die Versorgung von tracheotomierten Patienten" ("Recommendations for the care for patients who have undergone a tracheostomy").

From care with medical technical aids to the OR: Medical devices increase quality of life and save lives.

Sectoral interest group "Shortened Supply Channel" (FBVV)

FBVV aims to ensure that patients have access to medically necessary high-quality hearing aids through the abbreviated supply channel. Through the quality initiative "Verkürzter Versorgungsweg" ("Abbreviated Supply Channel", *www.hörgeräte-qvv.de*) the members have defined obligatory quality features for the supply of hearing aids. This includes a quality management manual and a compliance codex. In 2016, FBVV hosted a roundtable workshop and published an information card, a newsletter, and an information film in order to advise patients and contractual partners about this abbreviated and quality-assured alternative to the traditional supply channel for hearing aids.

PROJECT GROUPS

Project group "Neurostimulation" (PG Neuro)

The project group brings together the manufacturers of mostly implantable medical technologies that are applied to treat Parkinson's disease, epilepsy, migraine, cluster headaches, or chronic pain. The focus of its activities is on the promotion of the appropriate representation of these technologies in the reimbursement systems.

Project group "Surgical Incontinence" (PG opInko)

The project group has published patient education material about the surgical treatment methods of incontinence (*www.bvmed.de/inko-op*) in order to better inform patients that incontinence can be treated and modern medical technologies support this process.

Project group "Intermittent Self-Catheterization" (PG ISK)

The project group aims to guarantee high quality of care in the field of intermittent self-catheterization, ISC. In this respect, it works closely with the German-language Paraplegia Association (Deutschsprachige Medizinische Gesellschaft für Paraplegie, DMGP). In order to identify the supply needs of ISC patients, PG ISK is in the process of carrying out a patient survey. These activities are accompanied by the targeted public relations work of the campaign "Faktor Lebensqualität" ("Quality of Life Factor") (*www.faktor-lebensqualitaet.de*).

Project group "Medical Care and Remuneration" (PG MVV)

PG MVV issues the newsletter "MedTech ambulant" (*www.bvmed.de/medtech-ambulant*), which is published quarterly. It addresses in particular practice-based physicians by looking at issues and topics from the medical devices field that are specific and relevant for them. The issues dealt with in 2016 were the reform of the medical technical aids law, the new sections of the criminal law, therapies for incontinence care as well as the improvement of wound care structures. In addition, PG MVV updated its brochure on the framework for ambulatory surgery within the Statutory Health Insurance system (*www.bvmed.de/rahmenbedingungen-aop-2016*).

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

The core issue for PG Re-Use in 2016 was the forthcoming EU-wide regulation of the reprocessing of single-use devices as part of the EU Medical Device Regulation, MDR. The manufacturers call for a uniform level of patient protection that must be assured by the future requirements, regardless of who will be responsible for carrying out the reprocessing in any given case. Another issue the project group dealt with was the pending requirement, also in connection with the MDR, that with regard to reusable class I devices the questions of reusability, including the operating instructions, are to be assessed by a Notified Body.

The heroes of our body pride campaign "Körperstolz" (*www.bvmed.de/koerperstolz*): Thomas, Michael, Steffi, and Elke

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Our body pride heroes in an Berlin underground station and on a bridge crossing the Rhein river in Cologne

BVMed—Our Services for You

The German Medical Technology Association, BVMed, is an industry association that represents more than 220 industry and trade companies. Among the members of the association are 20 of the largest medical device manufacturers worldwide in the consumer goods sector. The scope of BVMed's members comprises the entire sector of medical dressings, medical technical aids such as ostomy and incontinence products or bandages, plastic disposable items such as syringes, catheters and cannulae, as well as the implants sector of intraocular lenses, hip, knee, shoulder and spinal implants, heart valves and defibrillators, and even artificial hearts. Homecare services, applications of nanomedicine and biotechnology procedures, such as tissue engineering (tissue replacement), are further fields of activity of its members.

As a trade association, BVMed promotes and represents the combined interests of the medical technology industry and trade companies. In various sectoral interest groups, focus groups, and working groups, the association offers its members a platform for a constructive dialog and exchange of views. BVMed represents the concerns of its member companies to policy makers and the public in general. This is achieved not only by information and public relations work, but also by participation in the development of laws, guidelines and standards. The services of BVMed can be subdivided into four sectors:

1. Organization

BVMed carries out the joint formation of opinion in more than 50 committees covering specific subjects. Further information can be found in this report starting on page 13. An up-to-date list of the BVMed working committees can be found at *www.bvmed.de/arbeitsgremien*.

2. Consultancy

The experts of BVMed are ready to offer accurate advice to members on such diverse topics as the Medical Devices Law, reimbursement for medical devices in hospital and ambulatory care, the Law on Advertising in the Healthcare System, standardization projects, or ordinances.

3. Information

BVMed offers a wide range of information through its internal as well as external communication, e. g:

INTERNAL COMMUNICATIONS

General circulars to all members, specific circulars for the individual expert committees, weekly newsletters, weekly infographics chart, monthly report in English, extranet for member companies, BVMed special events.

EXTERNAL COMMUNICATIONS

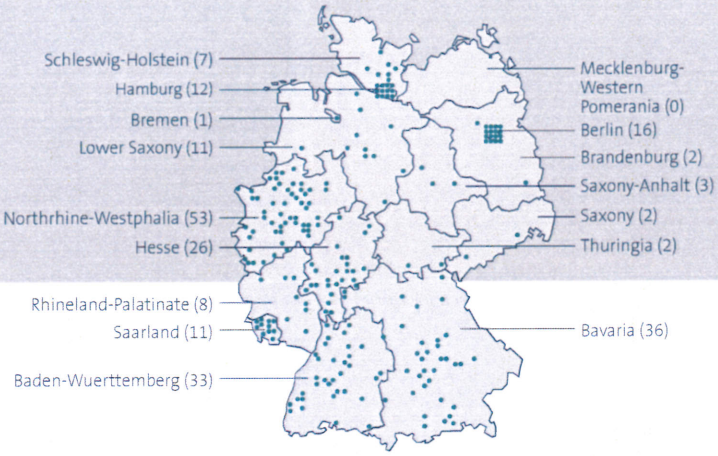
Website at *www.bvmed.de*, brochures, information cards, BVMed special events, MedInform conferences, training seminars (medical device consultants, SHI training, workshops on bidding / tendering law and CRM topics), press releases and conferences, press seminars, TV and radio service with film material,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

4. Representation

BVMed represents the interests of the medical technology sector. Important aspects of this work include political marketing and one-on-one interviews, the maintenance and support of networks, parliamentary discussion evenings, background discussions, participation in parliamentary hearings as well as representation in committees, advisory councils, commissions, etc.

How can your company join BVMed?

The terms and conditions for membership of BVMed are stated in article 3 of the BVMed statutes: *www.bvmed.de/satzung*. Applications for membership must be submitted in a letter to the managing director of BVMed. Please contact us. We look forward to helping you!



Interactive map of Germany showing the locations of our member companies at *www.bvmed.de*

As of April 2017: 224 members – current list available at www.bvmed.de

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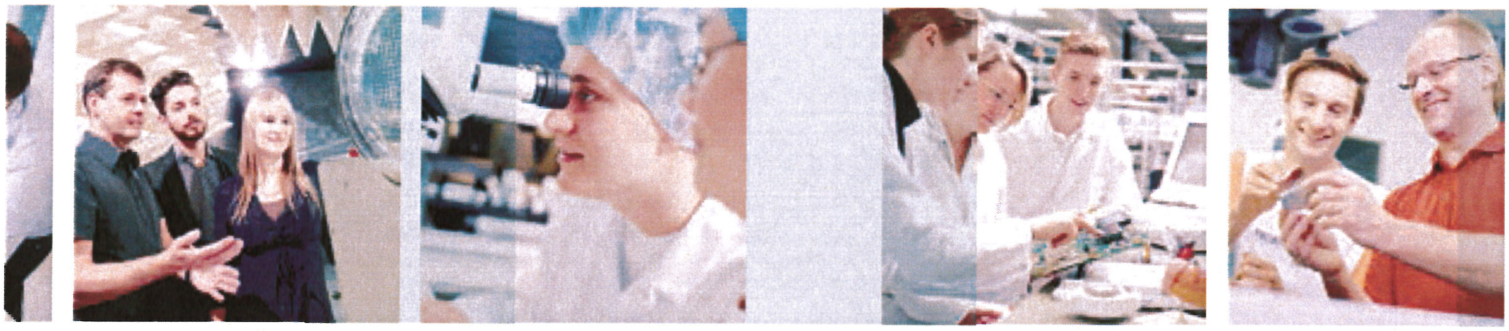

Diverse professions in medical technology: The industry employs over 210,000 people, ranging from development engineers, designers to production workers.

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Cover photo: Hernia mesh for repair surgery (Aesculap AG / B. Braun Melsungen AG)

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