

# BVMedReport № 03/16

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## Medical Device Regulation: "3 Years of Negotiations Are Enough"

Brussels. The informal dialogue negotiations on the new European Medical Device Regulation, MDR, will continue during the first six months of 2016 under the EU presidency of the Netherlands. Many of those involved shared the same opinion, MDR expert **Susanne Conze** of the German Federal Ministry of Health emphasized: "Almost 3 years of negotiations are enough. More consultations with experts will hardly lead to better texts." German government experts continue to oppose the planned scrutiny procedure, which is being viewed critically in particular by the medtech industry. Its proposed structure requires complex networks of clinical expert panels. More: [www.medinsight.de](http://www.medinsight.de)

## Benefit Assessment Without Gradual Innovations

Berlin. The Ministry of Health has published an explanatory statement on the medtech benefit assessment regulation. The comment defines expressions like "particularly invasive" or "long-term." It is expected that less than ten methods will be subject to the new proceedings conducted by the G-BA committee. Gradual innovations that do not lead to an essential change of the theoretical scientific concept of an already introduced method will not be assessed in terms of their benefit. More: [www.medinsight.de](http://www.medinsight.de)

## 5.2 Million Employees in the German Healthcare System

Wiesbaden. As of 2014, 5.2 million people were working in the German healthcare system, the Federal Statistical Office reported. This was two per cent more than in 2013.

## CDU Politician **Andreas Storm** to Become Head of DAK SHI Fund

Frankfurt. Former Minister of Health in the federal state of Saarland **Andreas Storm**, CDU, is to become the new head of the Statutory Health Insurance fund DAK Gesundheit. Mr. Storm will succeed **Prof. Dr. Herbert Rebscher** as chairman at the end of December.

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## "Joint Replacements Are a Success Story"

Berlin. Joint replacements are among the most successful medical procedures and called the "surgical operation of the century" by the renowned medical journal "Lancet." Endoprostheses enable patients to remain mobile and largely pain-free. More than 95 percent of the hip implants have a lifetime of more than 10 years and go along with a very low complication rate of less than two percent.

The causes of complications vary remarkably and,

based on register data and expert opinion, are in most cases not attributable to the implant itself. This was underlined by the German Medical Technology Association, BVMed. Reports attributing the high revision rates to defects of the respective medical device were "not based on facts, misleading and irresponsible as they make patients feel insecure," said BVMed CEO **Joachim M. Schmitt**.

More at [www.medinsight.de](http://www.medinsight.de).

## Heart Report Reveals Medtech Achievements

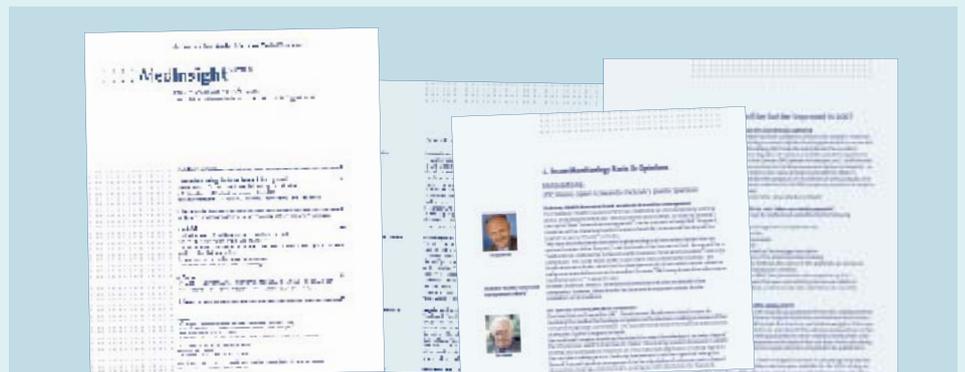
Berlin. The German Heart Foundation's Heart Report 2015 provides a tail wind for the medtech industry. The number of transcatheter implants of aortic valves continues to rise. Cardiac assist systems are becoming more and more durable. Furthermore, the mortality rate of children with heart defects is on the decline. The German Heart Report is compiled by the German Cardiac Society, DGK, the German Society for Pediatric Cardiology, DGPK, and the German Society for Thoracic and Cardiovascular Surgery, DGTHG.

A focus area of the report is the development in treating patients with stenosed aortic valves (aortic stenoses). The Heart Report shows that

the unprecedented success story of transcatheter aortic valve implantations, TAVI, in Germany continues. In 2014, TAVI procedures were performed in 13,264 patients with aortic valve stenosis. This is almost 3,000 more than in the previous year and means a significantly stronger increase than in 2013. There was still no reason to assume that TAVI might substitute surgical aortic valve replacement procedures, underlined DGK Chairman **Prof. Dr. Karl-Heinz Kuck**. For many years, the number of surgical aortic valve replacement procedures was around 10,000 per year. This had remained unchanged in 2014.

More at [www.medinsight.de](http://www.medinsight.de).

## MedInsight Germany: Latest News on Europe's Biggest Market!



MedInform has published a new issue of **MedInsight** Germany, a background report authored by the German medtech experts **Joachim M. Schmitt** and **Manfred Beeres** in cooperation with AdvaMed. **MedInsight** gives the latest news on Europe's biggest medtech market.

Topics of the new issue are e. g.: Medical Device Regulation: "3 Years of Negotiations Are Enough"; Benefit Assessment Without Gradual Innovations; Heart Report Reveals Medtech Achievements; Ortho-

pedics: "Joint Replacements Are a Success Story"; 5.2 Million Employees in the German Healthcare System; Innovation Fund: Money to Be Made Available Soon; Laumann: Funds Must Improve Quality of Medical Technical Aids.

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