

newsletter

Medical device safety

Medical progress would be unthinkable without the use of modern technology. But state-of-the-art medical devices and products can be a source of risk to patient and user alike.

Introduction Today, the safety of patients and aspects of claims prevention are a focal point of discussions in the light of the increasing complexity of modern medical equipment. The European Parliament and the Council of the European Union have issued four directives in the field of human medicine (90/385/EEC, 93/42 EEC, 98/79 EEC, 2000/70 EEC). These are the foundation upon which the national legislation of the individual member states is based. They also represent a linchpin for harmonising national regulations governing the safety and health of patients, users, and third parties when using medical products. Furthermore, these provisions aim to guarantee the free trade of these products across the single European market. In Germany, the Medical Products Act (MPG) and the Ordinance for Operators of Medical Products (MPBetreibV) govern the implementation of quality assurance measures when using medical products and the protection of patients and users. Switzerland as a non-EU country has to some extent geared its material product requirements to those of the EC by introducing its own Law on Therapeutic Products (HMG). The specific risks associated with the use of high-tech medical devices coupled with the frequently inadequate implementation of legal provisions on the part of hospitals and surgeries increase the relevance of this subject for the insurance industry.

Terms According to Directive 93/42/EEC (Medical Device Directive), a *medical device* is any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer, to be used for human beings for medical purposes and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. By way of its definition, the directive covers a wide range of medical products from the simple sticking plaster to highly complex equipment such as robots used in operations.

Medical devices are divided into four categories depending on their risk potential. Classification by intended purpose is carried out by the *manufacturers* themselves according to the EC guidelines, then verified and certified by "notified bodies".

The manufacturer of a medical device must fulfil the legal provisions. In addition, manufacturers and those bringing their products into circulation are obliged to implement a "vigilance system" that allows them to monitor the performance of devices after they have been sold.

The *operator* of a medical product is either a hospital's supporting authority or, in the case of a medical practice, the owner; in the latter case, the owner is also the *user* of the medical device.

A *user* is any person who performs activities either on or with the aid of a medical device on his or her own responsibility. As such, users include medical and nursing staff, paramedics and assistants.

Special national provisions govern the installation, operation and use of medical equipment. These give rise to numerous obligations applicable to manufacturers, operators and users, eg the duty to report to the competent national authorities any adverse incidents or near incidents stemming from the use of medical devices and products. Essentially, all medical products must bear the CE mark before they can be circulated within the European economic area. To obtain the CE mark, the device or product in question must fulfil a number of basic requirements in terms of performance and of the health and safety of users and patients.

Safety when using equipment

The safety of a medical device depends primarily on its technical state. But the qualifications, experience and expertise of users and persons responsible for carrying out necessary repairs and maintenance play a significant role, too. Organisational responsibility for ensuring that medical equipment is in good working order lies with the operator, who must provide users with the opportunity of attending appropriate training sessions in device operation. But the user, too, is also duty bound to request adequate instruction and to ensure that this is, in fact, provided before using the device. Before using any equipment, users must be satisfied that it is in full working order.

Problems and incidents

In 2002, the competent German authority (BfArM) received more than 2200 reports on incidents and near incidents in which patients were injured or placed at risk by malfunctioning devices and medical products. This represents a two-fold increase compared with the 1998 figure.

An analysis carried out some years ago by the Hanover School of Medicine showed that 63% of adverse incidents were the result of an operating error while 18% were due to inadequate maintenance.

More recently, discussions again centred on measures for minimising risk following media reports of a patient who died following heart surgery because a tube had been incorrectly attached to a heart-lung machine (Switzerland). Another patient died during an emergency operation after the tubes supplying the patient with laughing gas and oxygen had allegedly been mixed up following maintenance work on the equipment (Germany).

Technical possibilities; the human factor	The many new developments in the field of medical technology, eg telerobotics, or the manifold possibilities provided by nanotechnology may well lead to a widening of the gap between the state of the art and the expertise of medical personnel. Users have less and less time in which to attend training sessions and acquire the necessary know-how and practical skills. The consequence is an increase in the potential risk emanating from the field of medical technology.
Solutions	Given the frequency of operating errors, a structured programme of instruction and dedicated training sessions with practical elements are important steps towards reducing the number of medical incidents that lead to injury. Furthermore, processes must be put in place to ensure that all medical equipment is serviced and maintained regularly in accordance with the manufacturers' specifications.
Risk and patient information	<p>Patients are not always adequately informed about the risks of an impending operation. If the medical equipment required to perform a certain routine is still in its experimental stage or the safety of the procedure is not backed up by appropriate studies, it is essential that the patient be informed prior to surgery. Not explaining the experimental nature of a procedure to the patient beforehand can have grave consequences if complications occur and the medical staff are found to be in breach of their professional duty to inform.</p> <p>A current example is the robot-supported milling procedure performed during an operation for an artificial hip replacement. Here, the computer-assisted milling of a socket in the femur to house the prosthesis is still categorised as an experimental procedure. For this reason, the patient must be explicitly informed of the alternative of having the milling procedure performed manually by the surgeon. Due to subsequent complications, many patients who have had computer-assisted operations have brought charges against the responsible clinics. What is more, one attorney has announced his intention to press charges against the US-domiciled manufacturers of the equipment. At the start of the year, a leading German clinic for robotic hip solutions elected to discontinue work with the controversial procedure.</p>
Information for the underwriter	While the rapid technological progress in medical devices and products has paved the way towards new options for treatment, it has also increased the risks facing the medical profession. National legislation based on EU directives set out the duties and obligations that are to be observed by manufacturers, users and operators. Since any violations of these laws are punishable under civil and criminal law, they are relevant also in terms of liability law, with potential consequences for the liability insurer. Risk assessment in this area should verify, therefore, that the aforementioned laws have been implemented correctly and that the human factor adequately taken into account.

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