Chapter XLII
Medical and Biomedical Devices for Clinical Use

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ABSTRACT

Medical technology has been rapidly growing over the last decades. It is characterized by a constant flow of innovations and a high level of research and development. Many medical and biomedical devices have changed dramatically the way that medicine diagnoses and treats human disease, such as getting three-dimensional images of the internal human body. This chapter describes medical and biomedical devices, the regulatory framework about them, as well as the most active areas of research of medical technology. It also discusses the future trends of the medical industry and biosciences that constantly provide new possibilities of improving health care and patient quality of life.

INTRODUCTION

Medical technology is a science discipline that has been rapidly growing over the last decades. It is characterized by a constant flow of innovations and a high level of research and development. Many technological achievements have changed dramatically the way that medicine diagnoses and treats human disease. For example, the invention of computed tomography (CT), a noninvasive diagnostic technique, allowed clinicians to get three-dimensional images of the inside of the human body, and thus they can detect early many diseases that were impossible to detect before. Improved healthcare technology has presented many revolutionary medical devices that have reduced mortality and morbidity.

Medical devices range from simple ones like first-aid bandages to more sophisticated ones like positron-emission tomography (PET) scanners. Their main purpose is to improve the health status of patients and to support the prevention, diagnosis, and treatment of disease.

There are thousands of medical and biomedical devices, and this number is rapidly increasing. Therefore, a regulatory framework is essential to ensure the safety and efficiency

of the medical devices. In Europe, three directives have been applied by the European Commission in order to provide the guidelines for the development of new medical devices. These are the 93/42/EE directive on medical devices (MDD), the 90/385/EEC directive on active implantable medical devices (AIMDD), and the 98/79/EC in vitro diagnostic medical-device directive (IVDMDD).

SOME EXAMPLES OF MEDICAL DEVICES

The 93/42/EEC directive defines a medical device as:

[a]ny 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 on human beings for the purpose of:

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap,*
- *investigation, replacement or modification of the anatomy or of a physiological process,*
- *control of conception,*

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.

According to the Global Medical Devices Nomenclature (GMDN), the product range includes the following categories:

- Aids for disabled persons, for example, wheelchairs, crutches, standing supports, electrical beds, hearing aids, and stoma appliances
- Active and nonactive implantable devices, for example, stents, cardiac pacemakers, hip implants, neurostimulators, and insulin pumps
- Anaesthetic or respiratory equipment, for example, oxygen masks, anaesthesia breathing circuits, and gas delivery units
- Orthopaedic devices, for example, knee prostheses, orthopaedic shoes, and spinal corsets
- Dental devices, for example, dentistry tools and drills, alloys and resins, dental floss, and toothbrushes
- Electromedical and imaging equipment, for example, x-ray machines, scanners, electrocardiographs, monitors, lasers, and microscopes
- In vitro diagnostics, for example, devices for clinical chemistry, microbiology, immunology, and genetic tests
- Ophthalmic devices, for example, contact lenses, optometers, optical lenses, eye glasses, and ophthalmoscopes
- Surgical instruments, for example, scalpels, surgical drills, forceps, tubes, drains, sutures, and masks
- Biotechnological products, for example, tissue-engineered bones, cartilage, and skin
- medical disposables, for example, bandages, dressing, and syringes

An active implantable medical device (AIMD) according to the 90/385/EEC directive is a medical device as defined above that is at the same time both active and implantable.

A medical device is active if it "relies for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity." This