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Nota di contenuto	Medical Device Epidemiology and Surveillance; Contents; Foreword; Preface; Contributors; Acknowledgments; 1 Introduction; 2 Medical device regulation in the USA; Introduction; Premarket review; Marketing applications; Postmarket oversight; Conclusion; 3 Medical device epidemiology; Introduction; Features of medical devices that are relevant to epidemiology study design; Study designs for medical device epidemiology; Summary and recommendations; 4 Surveillance of adverse medical device events; Introduction; Rationale for surveillance; Surveillance based on adverse event reports Surveillance based on registriesActive surveillance; Necessary conditions for effective surveillance; Ideal AMDE surveillance program; Summary; 5 The Medical Product Surveillance Network (MedSun); Historical motivation; Initial considerations for the design of DeviceNet; MedSun basic design; Current status; Is MedSun successful in promoting the safe use of medical devices?; Epidemiologic considerations; Summary; 6 The National Electronic Injury Surveillance

System (NEISS) and medical devices; Description and history of NEISS; Potential uses and limitations of NEISS  
Utilization of NEISS to produce national medical device-associated adverse event estimates  
Potential for long-term utilization of NEISS for medical device surveillance; 7 Medical device nomenclature; Technical elements; Current terminologies; Applications of nomenclature; Future developments; 8 Data sources for medical device epidemiology studies and data mining; Introduction; Data sources; Surveillance databases; Registries; Automated large administrative databases; National surveys; Data mining; Future use databases for medical device epidemiology  
9 Ethical requirements and guidelines for epidemiological studies of medical devices  
Introduction; Bioethics foundations; US government human subjects protection regulations; HHS human subjects protection regulatory requirements; FDA human subjects protection regulations; Other professional ethical guidelines; Ethical requirements for medical devices epidemiologic studies; Future ethical requirements for epidemiologic studies; 10 An industry perspective: medical device epidemiology and surveillance; Introduction  
The product's life cycle: premarket (preclinical and clinical) and postmarket (PM) studies  
Postmarket studies; Summary; 11 Perspective from an academic on postmarket surveillance; Introduction; Adverse event reporting; Postmarket condition of approval studies and Section 522 studies; Industry use of information from adverse event reports; Academic opportunities; Summary; 12 Perspective from a pharmacoepidemiologist; Introduction; Review of literature; Contrasts with pharmacoepidemiology; Conclusions; 13 Medical device regulation and surveillance: perspective from the EU; Introduction  
Medical devices: the European directives and definitions

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## Sommario/riassunto

Medical devices are crucial in medical care today and device technology advances at a dizzying pace. Medical Device Epidemiology and Surveillance is the first book to provide an overview of medical device epidemiology and surveillance as well as perspectives from regulatory agencies, the medical device industry, the health insurance industry and academia. The book is edited by experts from the US Food and Drug Administration with contributions from experienced specialists working in this field in the US and around the world. It features chapters describing broad themes in medical

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