

BME 4470/6470 – Design of Medical Devices

Course Description

Introduction to the development, design and construction of medical devices, with consideration of design concepts, materials, regulatory requirements, and other constraints. Includes computational analysis of devices using gait profile and applicability of engineering biomaterials for specific applications.

Undergraduate/Graduate level - 3 credit hours.

*Homework and exams are specific for the graduate students. In them concepts are explored at a deeper level than for undergraduates.

Course Learning Objectives

Students enrolled in this course will learn to:

apply design concepts to medical device development

- use engineering tools and materials in medical device design
- identify form, fit and functional aspects of medical devices
- seek and reduce data to create medical devices

Course Learning Outcomes

Upon successful completion of this course, students can:

- apply design concepts to medical device development
- use engineering tools and materials in medical device design
- identify form, fit and functional aspects of medical devices
- seek and reduce data to create medical devices

Tentative Weekly Schedule

Week 1	General introduction, introduction to 5 units of the design of medical devices course
Week 2	Scope, medical devices by the number, WHO/FDA and European regulatory practices
Week 3	WHO definition of medical device, classes of devices, clinical testing, and risk assessment
Week 4	Medical Devices: Introduction to cardiovascular devices
Week 5	Design of respiratory/artificial kidney devices
Week 6	Pacemakers and orthopaedic devices. Students design heart valves and 3D print their designs and/or orthopaedic device.
Week 7	Design considerations in the construction of medical devices with engineering materials
Week 8	Introduction to metals, polymers, ceramics and composites
Week 9	Biocompatibility and mechanical behavior of materials
Week 10	Fundamentals of mechanical design of medical devices, introduction to stress/strain and failure theories
Week 11	Static versus dynamic design rules
Week 12	Introduction to specifications such as requirements of ASTM/ISO in medical device
Week 13	Application of concepts to design of medical devices, e.g., finite element analysis of plates, total joint implants, heart valve, cochlear implant lead etc
Week 14	Continuation of hands on work with medical devices
Week 15	Finals

