

BME 7371 – Failure Analysis of Medical Devices

Course Description

Failure modes of medical devices. Common medical devices such as total joint replacement implants, fixation plates and screws, intermedullary nails, pace makers, other implantable products. Procedures to conduct failure cause investigations within the guidelines developed by regulatory agencies.

Graduate level – 3 credit hours

Course Learning Objectives

Students enrolled in this course will learn to:

- Prepares the students to learn failure modes of medical devices.
- introduces the learner about the common medical devices such as total joint replacement implants, fixation plates and screws, intermedullary nails, pace makers, other implantable products such as breast implants.
- Students learn the procedures to conduct failure cause investigations within the guidelines developed by regulatory agencies that may lead to destructive testing and analysis.
- Student works on an independent medical device failure analysis project and prepares a final report (15th week) and presents the findings to the class. This course also uses instructor's research on various topics.

Course Learning Outcomes

Upon successful completion of this course, students can:

- Understand the failure modes of medical devices.
- Understand about the common medical devices such as total joint replacement implants, fixation plates and screws, intermedullary nails, pace makers, other implantable products such as breast implants.
- Understand procedures to conduct failure cause investigations within the guidelines developed by regulatory agencies that may lead to destructive testing and analysis.
- Work on an independent medical device failure analysis project and prepare a final report and present the findings to the class.

Tentative Weekly Schedule

Week 1	General introduction
Week 2-4	Concepts, theory and examples of failure analysis, and case assignments
Week 5-13	Students perform analyses of failure cases, lab training
Week 7,9,11	Discussion with the instructor about the project, reporting, and formatting, review handbooks
Week 14	Final report submission and final presentation Report has to be in a paper format for International Journal of Failure Analysis
Week 15	Final Exam