Course Syllabus

- **Course Information**

  Course Number/Section: BMEN 4360.001 – Biomaterials and Medical Devices
  Term: Spring 2026
  Days &Times: Class will meet on Mondays and Wednesdays from 10:00 AM - 11:15 AM CT.
  Classroom: GR 2.530

- **Instructor Information**

  Instructor: Dr. Danieli Rodrigues

  Office Phone: 972-883-4703
  Office: BSB 12.929
  E-mail: danieli@utdallas.edu
  Office hours: Mondays 2:00-3:00 PM. This is an open time for students to meet one-to-one with the instructor to go over assignments, class content, or talk about professional opportunities, career, etc.

  Teaching Assistant: Krishna Prajapati
  E-mail: Krishna.prajapati@utdallas.edu
  Office hours: TBD

- **Class Participation**

  Students who fail to participate in class regularly are inviting scholastic difficulty. A portion of the grade for this course may be directly tied to your participation in this class. It also includes engaging in group or other activities during class that solicit your feedback on homework assignments, readings, or materials covered in the lectures. Successful participation is defined as consistently adhering to University requirements, as presented in this syllabus. Failure to comply with these University requirements is a violation of the Student Code of Conduct.

  Note: this is a highly interactive and engaging class. Although instructor follows the lecture plan and structure detailed in this syllabus, this class is supposed to be discussion-based; thus, in class participation is essential for student success. The instructor will use multiple resources to promote learning and exposure to current topics in the field. Different elements will be used as teaching tools: (1) class notes: students are supposed to take notes during class discussions as it is impossible to summarize all content presented in class in slides or written notes. It is each student's responsibility to take their own notes as they understand topics discussed and presented in class; (2) slides: class content is summarized in slides; (3) literature: instructor will share on eLearning additional materials such as journal articles, short readings, and detailed answer keys for quizzes. The instructor also suggests a list of textbook resources for those who want to follow a textbook; (4) in class active discussions of clinical cases, teamwork, and in class quizzes: these activities will be done in a regular basis to monitor learning and promote exchange of ideas and "outside the box thinking" when evaluating a clinical case or design problem. Instructor will work with groups and there will be interactions among different groups to solve a problem.

- **Class Recordings**

  The instructor may record meetings of this course. Any recordings will be available to all students registered for this class as they are intended to supplement the classroom experience. Students are expected to follow appropriate University policies and maintain the security of passwords used to access recorded lectures. **Unless the Office of Student AccessAbility has approved the student to record the instruction, students are expressly prohibited from recording any part of this course. Recordings may not be published, reproduced, or shared with those not in the class, or uploaded to other online environments except to implement an approved Office of Student AccessAbility accommodation**. If the instructor or a UTD school/department/office plans any other uses for the recordings, consent of the students identifiable in the recordings is required prior to such use unless an exception is allowed by law. Failure to comply with these University requirements is a violation of the Student Code of Conduct.

- **Course Description**

  Introduction to the field of biomaterials used in the design of medical devices and to augment/replace soft and hard tissues. Discussion of bulk properties, clinical applications, and *in vivo* behavior of different classes of natural and synthetic materials. Analysis of biological response and biocompatibility, degradation and failure processes of implantable biomaterials/devices. Overview of regulatory compliance and performance requirements for commercialization of medical devices.

  Students will become familiar with several classes of biomaterials and their bulk and surface properties. Lectures will discuss design and performance requirements of implants, structure-property relationships for synthetic and biological materials, and static and dynamic properties of biomaterials.

- **Course Learning Objectives:**

- **CLO1**: Report contemporary challenges with the design and development of artificial implants using current literature (SO: 3).
- **CLO 2**: Assess the performance of biomaterials and their interactions with the biological environment (SO: 1).
- **CLO 3**: Understand the regulatory environment governing development, performance and commercialization of medical devices (SO: 4).
- **CLO 4**: Recognition of professional responsibility through evaluation of clinical cases and by researching standard testing procedures and their relationships to US and European regulations (SO: 4).

- **Suggested Textbooks**

  Biomaterials Science: An Introduction to Materials in Medicine. Willian Wagner et al. 2021, 4th edition. (This is the most comprehensive book for this class. It covers all aspects from fundamental information to regulatory topics). The older version of this book (2004) as indicated below is also a great option and it is more economic.

  Biomaterials Science: An Introduction to Materials in Medicine. Buddy D. Ratner et al. 2012, 3rd edition; or 2nd edition (2004).

  Introduction to Biomaterials: Basic Theory and Engineering Applications. C. Mauli Agrawal, Joo L. Ong, Mark R. Appleford, Gopinath Man. Cambridge University Press 2014, 1st Edition.

Note: the acquisition of a textbook is not required. Lecture notes, articles, and handouts will be distributed via eLearning. Lectures will use a combination of materials from several books, articles and other sources.

- **Class Materials**

The instructor will provide class materials that will be made available to all students registered for this class as they are intended to supplement the classroom experience. These materials can be downloaded during the course; however, these materials are for registered students' use only. Classroom materials may not be reproduced or shared with those not in class or uploaded to other online environments except to implement an approved Office of Student AccessAbility accommodation. Failure to comply with these University requirements is a violation of the Student Code of Conduct.

- **Websites**

Course Materials (power point lectures, updated syllabus, handouts, project guidelines and information) will be available on eLearning.utdallas.edu.

- Other important resources:
  - *FDA*: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm
  - Testing standards for devices and biomaterials can be found at: http://www.iso.org/iso/home.html http://www.astm.org/

- **Technical Requirements**

In addition to a confident level of computer and Internet literacy, certain minimum technical requirements must be met to enable a successful learning experience. Please review the important technical requirements on the Getting Started with eLearning webpage.

- **Course Access and Navigation**

This course content can be accessed using your UT Dallas NetID account on the eLearning website. Please see the course access and navigation section of the Getting Started with eLearning webpage for more information. To become familiar with the eLearning tool, please see the Student eLearning Tutorials webpage. UT Dallas provides eLearning technical support 24 hours a day, 7 days a week. The eLearning Support Center includes a toll-free telephone number for immediate assistance (1-866-588-3192), email request service, and an online chat service.

- **Communication**

This course utilizes online tools for interaction and communication. Some external communication tools such as regular email and a web conferencing tool may also be used during the semester. For more details, please visit the Student eLearning Tutorials webpage for video demonstrations on eLearning tools. Student emails and discussion board messages will be answered within 2 working days under normal circumstances.

- **Server Unavailability or Other Technical Difficulties**

  The University is committed to providing a reliable learning management system to all users. However, in the event of any unexpected server outage or any unusual technical difficulty which prevents students from completing a time sensitive assessment activity, the instructor will provide an appropriate accommodation based on the situation. Students should immediately report any problems to the instructor and contact the online eLearning Help Desk. The instructor and the eLearning Help Desk will work with the student to resolve any issues at the earliest possible time.

- **Pre-requisites/Core-requisites**

  BMEN 2320, CHEM 1312

- **Course Content Outline and Tentative Schedule:**

  01/22, 01/26, 01/28, 02/02

1. Course Overview and Introduction

1.1. Instructor and TAs Introductions
1.2. Course objectives, expectations and assessment: overview of syllabus
1.3. First survey
1.4. Introduction to biomaterials science
1.5. Brief history of biomaterials: surgeon-era to engineered biomaterials
1.6. Overview of current selected clinical applications
1.7. Overview of the current medical device industry

02/04, 02/09, 02/11, 02/16

2. Basic Properties of Biomaterials

2.1. Bonding, interatomic, intermolecular, surface interactions
2.2. Bulk properties: microstructure, strength, deformation, failure, fracture
2.3. Surface properties: hydrophilic and hydrophobic interactions, surface charges

3. Selected Classes of Materials Used in Medicine

02/18, 02/23, 02/25, 03/02

3.1. Metallic biomaterials:

- *general characteristics and desirable properties*
- *fabrication and processing*
- *surface: oxide film formation and surface modification techniques*
- *characterization: bulk and surface*
- *main metallic alloys used in implantable devices:*
- *selected applications: Ti, SST, Nitinol, CoCr, Mg, Ta: groups discussion/presentations*

03/04, 03/09

3.2. Ceramic and composite biomaterials:

- *general characteristics and properties*
- *types of bioceramics*
- *fabrication and strengthening*

- *characterization: bulk and surface*
- *selected applications: calcium phosphates, alumina, zirconia, natural and synthetic hydroxyapatite: groups discussion/presentations*

03/11

Exam 1 or TBD

03/23, 03/25, 03/30, 04/01, 04/06, 04/08

3.3. **Polymeric biomaterials**:

- *general information*
- *basic principles: molecular and chemical structure, molecular weight and polydispersity*
- *physical behavior*
- *synthesis*
- *characterization: bulk and surface*
- *selected applications: inert, degradable, hydrogels: groups discussion/presentations*

04/13, 04/15, 04/20

5. Biomaterials Degradation in the Biological Environment

5.1. Working environment of implants in the body
5.2. Chemically assisted degradation
5.3. Mechanically assisted degradation
5.4. Synergistic failure modes
5.5. Review of clinical cases of implant failure (selected fields: cardiovascular, neural, tissue, arthroplasty, dental, etc.): project presentation – critical review and discussion of selected medical device recalled/or displaying high rates of failures in the field

04/22, 04/27

6. Biocompatibility

6.1. Biological response to biomaterials, wound healing, foreign body reaction
6.2. Blood-material interactions
6.3. Toxicity, hypersensitivity
6.4. Tumors associated with biomaterials and implants
6.5. Biofilms

04/29

7. Special Considerations for Implantable Devices and Biomaterials

7.1. Sterility and patient safety
7.2. Device failure mode analysis
7.3. Regulatory compliance

05/04

Exam 2 or TBD

- **Grading Policy**
  - **Exam 1:** 30%
  - **Exam 2**: 30%

- **In class pop up quizzes, team quizzes, quiz questions presentations:** 30%
- **Presentation/team discussion of recalled implant/failure mode case**: 10%

%	100-93.0%	92.9%-90.0%	89.9%-87.0%	86.9%-83.0%	82.9%-80.0%	79.9%-77.0%	76.9%-73.0%	72.9%-70.0%	69.9%-67.0%	66.9%-63.0%	62.9%-60.0%	≤59.9
Letter Grade	**A**	**A-**	**B+**	**B**	**B-**	**C+**	**C**	**C-**	**D+**	**D**	**D-**	**F**

- **Course Assessment: PLEASE READ THIS SECTION CAREFULLY**

  - **Exams**: Two exams are scheduled during the semester. Exams are not cumulative and will cover the previous content up to the week leading to the exam. There will be one chance for a makeup exam (scheduled during finals week). This exam will be offered to those students who missed exam 1 or 2 **due to a documented reason**. The makeup exam will be cumulative and will replace the missing grade (for exam 1 or 2). The format will be the same as exams 1 and 2, just the content will cover all topics.
  - **In class pop up quizzes, team quizzes, quiz questions presentations**: quizzes will be given on a weekly/biweekly basis following lectures or discussion of clinical/device application cases. Quizzes will be done on an individual basis or in teams of 3 students, and they can be scheduled or unannounced. This semester, we will have different quiz modalities: (1) individual or (2) group applications: students working on team questions should be ready to present their answers to the entire class. Two or three groups will be drawn during each activity to explain answers. This will particularly happen at the end of each chapter when we discuss device/biomaterials applications for each material category.
  - **Presentation/team discussion of recalled implant/failure mode case**: teams will select one clinical application/device/biomaterial that has a reported recall or failure mode. The team will critically review/critique the article/material summarizing: (1) device/biomaterial background (2) clinical application (3) identification of failure modes (4) course of action (5) thoughts on what could have done to mitigate failure/problem in the field. Teams will submit and present a power point with a maximum of 10 slides to the instructor/or TA. This can be scheduled with the instructor (during office hours) or TA during the month of April.

- **Course & Instructor Policies**

  - **Make up exams:** Students are expected to take exams on posted dates and as announced by the instructor. Unavoidable conflicts must be communicated to the instructor ahead of time. Missed exams without e-mail notification in advance of the absence will result in a grade of zero for the assignment or test.
  - **Late work:** No late work will be accepted. Unavoidable conflicts must be communicated to the instructor ahead of time**. PLEASE FOLLOW SCHEDULES AS POSTED.**
  - **Class attendance:** Class attendance is expected as this is a fast paced and highly interactive course. The instructor encourages questions from students during lectures. Please access eLearning on a weekly basis for lecture slides, activities including quizzes, and assignments submission.
  - **Classroom citizenship:** Each student is expected to participate in quizzes and associated discussions. Instructor will mark student participation in class during lecture/discussions.

- **UT Dallas Syllabus Policies and Procedures**

The information contained in the following link constitutes the University's policies and procedures segment of the course syllabus. Please go to http://go.utdallas.edu/syllabus-policies for these policies.

The descriptions and timelines contained in this syllabus are subject to change at the discretion of the Professor.