

San José State University, College of Engineering
Department of Biomedical, Chemical and Materials Engineering
BME 168, Medical and Biological Polymers, Fall 2022

Course and Contact Information

Instructor:	Melinda (Mindy) Simon
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Office Hours:	T 11am-12pm, in person (E 233 M) F 12:30-1:30, Zoom
Class Days/Time:	Monday : 10:30 - 11:20 AM Wednesday: 10:30 - 11:20 AM (same Zoom link for all class sessions)
Classroom:	Engineering Bldg, Room 329
Prerequisites:	BME 68 or MATE 25 with "C-" or better. Instructor consent.

Course Format

Technology Intensive, Hybrid, and Online Courses

The course adopts a traditional lecture format as a primary teaching method, combined with in-class discussions and occasionally problem-solving sessions. In class each student is required to have an internet-connected device (e.g. smartphone, tablet, laptop computer) to be used exclusively for learning-related activities, including the iClicker technology available at SJSU.

This course incorporates a required lab component (BME 168L).

Faculty Web Page and MYSJSU Messaging

Course materials such as syllabus, handouts, notes, assignment instructions, etc. can be found on the Canvas learning management system course website. All communications relevant to the course will be sent out using the Canvas messaging system (Canvas email and announcement board). Students are responsible for regularly checking with the messaging system through Canvas to learn of any updates.

Course Description

Polymer applications in medical devices and equipment, biological and biodegradable polymers, structure-processing-properties relationships, chemistry, thermal transitions, mechanical, electrical and optical properties, clinical outcomes and complications arising from use of polymers, regulatory framework for polymer use in humans.

Course Goals

The fundamental objective of this course is to educate engineers on the importance of understanding the interaction between synthetic and biological materials. Of particular importance here is the role of the structure-processing-property relationship, and how this plays a key role in the design, manufacture, clinical performance, long-term reliability and quality/regulatory assurance of medical and implant devices.

Course Learning Outcomes (CLO)

Upon successful completion of this course, students will be able to:

- **Define** short term and long term medical applications for biomaterials made of natural and synthetic polymers.
- **Explain** significant current problems in medicine that require development of versatile and sophisticated biomaterials.
- **Demonstrate** knowledge of the use of different material types used in biomedical implants and biomedical devices.
- **Define, synthesize and apply** principles learned towards materials selection, including trade-off issues and evaluations, for biomedical implants and devices.
- **Explain** mechanical and surface properties of biomaterials.
- **Describe** experimental methods for the characterization of mechanical and surface properties of biomaterials.
- **Comprehend** the design principles involved in biomedical implants and devices, especially issues of biocompatibility with living tissue, and principal mechanisms of material/implant interaction with tissues.
- **Explain**, for degradable and stable polymers, the host response upon implantation and how it impacts prosthetics and implanted devices.
- **Explain** the physical and chemical degradation of polymeric materials in the biological environment.
- **Comprehend** the application of shape memory polymers in minimally invasive medical devices, including applications in design considerations and evaluations for materials selection.
- **Define and describe** the steps in the synthesis and the properties of synthetic and natural polymers and their applications as biomaterials.
- **Comprehend** surface treatments used for surgical and medical devices and implants, including laser treatment, heat treating, mechanical polishing, and applications of coatings.
- **Evaluate and discuss** ethical concerns relevant to biomaterial science.
- **Write** a cohesive and informative paper on a subject related to polymer use in medical devices, including an explanation of the materials science principles, biocompatibility considerations, design considerations, and other pertinent factors.
- **Prepare** and deliver a professional presentation, using presentation software, to an audience of peers.

Required Texts/Readings

Buddy D. Ratner et al., Editors, Biomaterials Science – An Introduction to Materials in Medicine, 3rd Edition, Elsevier Academic Press. –available as an E-book for free through <https://library.sjsu.edu/> (search for title name)

Additional reading materials (optional) are listed on the Canvas site

Other technology requirements

iClicker Polling

You will have several options available to participate in clicker sessions:

iClicker Polling App: Allows you to use your smart phone, tablet, or even laptop in class as a clicker to participate.

Please create an account at iClicker if you do not have one already. If you have an iClicker account and have access to the Canvas page for this course, you will be automatically added to the iClicker page for this course so that you can participate in the quizzes.

Library Liaison

Megwalu, Anamika

Phone: 408-808-2089

Email: anamika.megwalu@sjsu.edu

Course Requirements and Assignments

SJSU classes are designed such that in order to be successful, it is expected that students will spend a minimum of forty-five hours for each unit of credit (normally three hours per unit per week), including preparing for class, participating in course activities, completing assignments, and so on. More details about student workload can be found in University Policy S12-3 at <http://www.sjsu.edu/senate/docs/S12-3.pdf>.

Attainment of the learning objectives (as listed above) will be assessed via homework, laboratory activities, in-class design problems, quizzes, two mid-term examinations, and the term paper and presentation.

Homework assignments

Students are expected and encouraged to work together on assignments. However, submitted homework should be individual work. Homework must be submitted via Canvas by the deadline. Your homework should be uploaded as a single file, easily readable without zooming in or out or rotating the page. Homework submissions that do not comply with these requirements will be assessed a 20% penalty from the maximum score.

Late submissions will be assessed 1.5%/hour off of the maximum possible score. *Absolutely no homework will be accepted via email* to the instructor or the grader.

Laboratory assignments

Students are expected to attend all laboratory sessions over the course of the semester. One excused absence from a laboratory session is acceptable for emergency purposes only (and this requires a doctor's note). If a session is missed, it needs to be made up during another lab section meeting time. Students are expected to arrive on-time to their laboratory session meeting. Late arrivals will incur penalties applied to the lab report grade.

Students will prepare laboratory reports, based on post-lab assignments, **working in groups**. The report must include an Acknowledgments section indicating the specific contributions of each student. Students with no contribution will receive no credit for the report.

Reports must be turned in at the **beginning of class** on the due date. **Late submissions** will be assessed 10%/day off of the maximum possible score, and will be accepted up to 3 days late.

Class participation assignments

There will be regular in-class participation problems that you will work on individually or in groups. Some problems will request a response with iClicker and others will require a short submission via Canvas. I will not

use iClicker to keep track of attendance. Refer to the Grading Policy and Student Technology Resources section for additional details on iClicker. **If you cannot attend class synchronously (i.e. at the scheduled time), please email the instructor within the first week of class to make alternate arrangements.**

Examinations

There will be two mid-semester examinations and one final examination. The midterm examination will cover the entire course material covered until the time of the examination (i.e. comprehensive). The final examination will cover the entire course material covered during the entire semester (i.e. comprehensive). Examinations may include multiple-choice questions, open-ended questions, and problems. During the exam, students can have only a non-programmable scientific calculator. Internet-connected devices, books and notes are not allowed. The dates of the examinations are indicated in the Lecture Schedule.

Term paper

All students are required to write a term paper on a specific material used for medical devices, and present it in lab during a dedicated session. The requirements for the term paper and the evaluation criteria will be posted on Canvas. Students will work in groups of 2, which they will form with members of their laboratory section. The term paper must include an Acknowledgments section indicating the specific contributions of each student. Students with no contribution will receive no credit for the term paper. The term paper and presentation according to a rubric that will be made available at the beginning of the semester.

The deadline for submitting the term paper is November 21, at 11:59 p.m. Presentations are scheduled for the week of November 28, 2022 (*subject to change with fair notice*), during the laboratory hours.

The term paper must be prepared in accordance with the Biomedical, Chemical & Materials Engineering Department's Thesis Guidelines (posted on Canvas in the "Files" section). One electronic copy of the term paper must be submitted by the indicated deadline. Acceptable file formats are: .doc, .docx, .pdf.

Students must cite any and every source of data or information used in the term paper. Quoting *verbatim* (i.e. "copy and paste") from papers, textbooks, websites or other is strongly discouraged. **Very limited use** of verbatim quotes is acceptable **only if** (1) the quoted text is short, (2) quote marks are used to delimit the quoted text, and (3) an appropriate reference is provided, with a citation number added immediately after the quoted text. Failure to comply with this requirement may be interpreted as plagiarism, which constitutes a violation of academic integrity. All term paper submissions will be automatically scanned in Turnitin to locate matching or similar text within the paper. The instructor will decide whether there is plagiarism case-by-case, in which case academic and administrative sanctions will be assigned according to the University Academic Integrity Policy S07-2 (<http://www.sjsu.edu/senate/docs/S07-2.pdf>).

Please view the video on plagiarism at the library's website for more information:

<http://libguides.sjsu.edu/plagiarism>

Late submissions are strongly discouraged. However, under *exceptional* circumstances and pending instructor approval, in case of late submission of the term paper, points will be deducted as follows:

- One day late: -10%
- Two days late: -25%
- Three days late: -50%

No submission will be accepted later than three days after the deadline. Please note that this late submission policy only applies to the term paper assignment.

NOTE that University policy F69-24 at <http://www.sjsu.edu/senate/docs/F69-24.pdf> states that “Students should attend all meetings of their classes, not only because they are responsible for material discussed therein, but because active participation is frequently essential to insure maximum benefit for all members of the class. Attendance per se shall not be used as a criterion for grading.”

Grading Information

Letter Grades:

A+	> 97%
A	> 93% – 97%
A-	> 90% – 93%
B+	> 87% – 90%
B	> 83% – 87%
B-	> 80% – 83%
C+	> 77% – 80%
C	> 73% – 77%
C-	> 70% – 73%
D	> 60% – 70%
F	< 60%

Determination of Grades

Grades will be determined based on all the assignments and examinations, weighted as reported below:

Homework	5%
Class participation activities	5%
Midterm I	15%
Midterm II	15%
Final Examination	25%
Term Paper	15%
Term Paper Presentation	5%
Laboratory	15%
iClicker ($\geq 75\%$ participation)	+2%

Participation with iClicker will be the only extra credit assignment. Participating in at least 75% of the quizzes over the semester is necessary to obtain the extra credit.

Absence during examinations, without prior approval, will result in a zero. Prior approval will be given only under exceptional circumstances. Please contact the instructor as soon as possible if you have such a situation.

Note that “All students have the right, within a reasonable time, to know their academic scores, to review their grade-dependent work, and to be provided with explanations for the determination of their course grades.” See University Policy F13-1 at <http://www.sjsu.edu/senate/docs/F13-1.pdf> for more details.

Classroom Protocol

Attendance and arrival times

Students are expected to be signed in by the time the class begins. Many classes will begin with the iClicker session, and these participation points cannot be “made up” if a portion of class is missed. Attendance in class is

not mandatory and shall not be used per se as a criterion for grading. However, class attendance and participation are highly recommended.

Behavior

Students should remain respectful of each other at all times. Interruptive or disruptive attitudes are discouraged. While in the classroom, the use of electronic devices (laptops, tablets, smartphones) should be limited to activities closely related to the learning objectives. While in the classroom, electronic devices should not be used for personal communication, included messaging and use of social media. All cell phones must be silenced prior to entering the classroom.

Students will respect a diversity of opinions, ethnicities, cultures, and religious backgrounds. Students will treat online discussions with their peers as if they were in-class, face-to-face interactions.

Safety

Students should familiarize themselves with all emergency exits and evacuation plans.

University Policies

Per University Policy S16-9, university-wide policy information relevant to all courses, such as academic integrity, accommodations, etc. will be available on Office of Graduate and Undergraduate Programs' Syllabus Information web page at <http://www.sjsu.edu/gup/syllabusinfo/>

BME 168 – Medical and Biological Polymers, Fall 2022, Course Schedule

Tentative Course Schedule *(subject to change with fair notice)*

Week	Date	Topics, Readings	Term paper deadlines
1	08/22	Intro to Biomaterials. The Syllabus	
1	08/24	Biomaterial Req., Molecular Origins of Biomat. Behavior (I.1.2)	
2	08/29	Mechanical Properties of Biomaterials I (I.1.3)	
2	08/31	Mechanical Properties of Biomaterials II	
3	09/5	NO CLASS – Labor Day	Group, topic assignments
3	09/7	Mechanical Properties of Biomaterials III	
4	09/12	Introduction to polymers (I.2.2)	
4	09/14	Introduction to polymers (I.2.2)	
5	09/19	PE, PMMA, PU (I.2.2A)	Progress Report 1 due
5	09/21	Silicones, Fluor., Acrylics (I.2.2B, C, D, II.5.18)	
6	09/26	Degradation of Synthetic Polymers (II.4.2)	
6	9/28	Midterm I	
7	10/3	Surface modification (I.2.12)	
7	10/5	Surface characterization (I.1.5)	
8	10/10	Natural Polymers (II.1.5, Agrawal Ch. 8)	
8	10/12	Engineered Natural Polymers (I.2.7)	
9	10/17	Hydrogels & smart polymers (I.2.5, I.2.11)	
9	10/19	Degradable, resorbable, smart polymers (I.2.6, I.2.11, II.4.3)	
10	10/24	Case study: Cardiovascular devices	Progress Report 2 due
10	10/26	Sterilization of Med Devices (III.1.2, Agrawal Ch.10)	
11	10/31	Biocompatibility testing, Biological Responses to Biomaterials (II.2.1 & II.2.2)	
11	11/2	Blood Interactions with Biomaterials/Thrombogenicity (II.2.6)	
12	11/7	Midterm II	
12	11/9	Device-Related Infections (Ratner, II.2.8)	
13	11/14	Failure Mode Analysis (III.1.4)	
13	11/16	Special Topic: Drug Delivery Systems (II.5.16)	
14	11/21	Special Topic: Tissue Engineering (II.6.2)	Term paper due
14	11/23	NO CLASS- Thanksgiving	
15	11/28	Special Topic: Bioprinting	
15	11/30	Case study: Soft implants	
16	12/5	Final exam review	
		Final exam – Time and data TBD by SJSU: https://www.sjsu.edu/classes/final-exam-schedule/fall-2021.php	