Massachusetts Institute of Technology MIT 2.782, HST.524 Spring 2026
Tuesdays and Thursdays, 11:00-12:30 PM; Room: 5-134
Canvas Website: https://canvas.mit.edu/courses/36428
Zoom: https://mit.zoom.us/j/98915343688
Lecture Recordings:
https://www.dropbox.com/scl/fo/nk3k04dql41zjx0l6ii98/ANiXVulErH6uWsR1EC0kbX8?rlkey=dra5kubjth2qljc4qxh5qmscu&st=3aylda1i&dl=0

DESIGN OF MEDICAL DEVICES/IMPLANTS

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Co-Instructor: TBN
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SYLLABUS

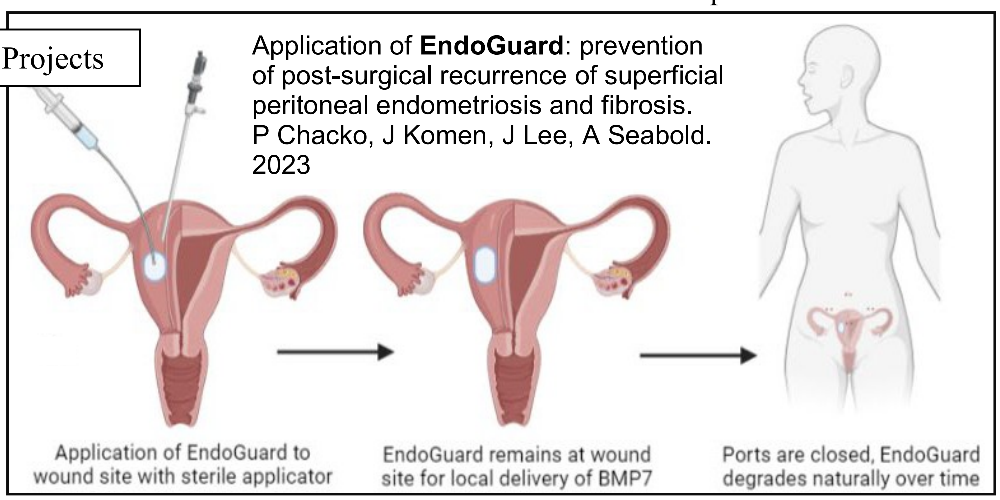
DESCRIPTION

A design subject that teaches: rational approaches to the development of an implantable/injectable medical device to treat a specific well-defined clinical problem; and the steps to start a company to make it available to the patient. Students work in teams of 3 to develop the design for an FDA Class III medical device or combination product (incorporating drugs and/or biologics). The emphasis is on the science and engineering underlying the design of novel treatments for problems in any one of the 78 organs of the body.

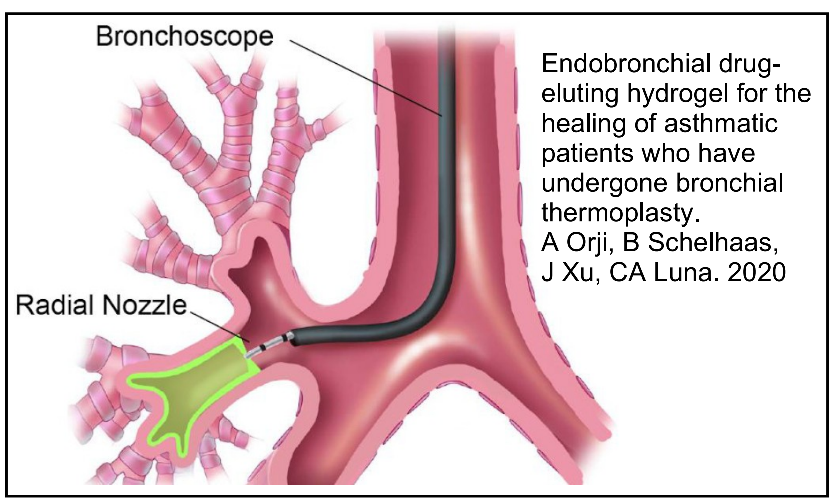
All classes will be held in-person, and presented on Zoom for remote lecturers and for students with excused abscences; all classes will be recorded on Zoom and an in-room camera. All content will be posted on Canvas.

- Paradigm for design of medical devices
- Principles for full or partial *permanent replacement* or *regeneration* of tissues and organs, with select case studies
- Considerations of anatomy, histology (***makeup of tissues and organs***), physiology, pathology
- An understanding of the newly acquired knowledge of the cell and molecular biology that underlies the problem, and that provides ***targets for treatment***
- The 3 tools for facilitating healing (including prevention, suppresion of recurrence, degradation, or harnessing of ***scar***) and ***regeneration***: ***biomaterials***; ***cells*** and their constituents; and ***regulatory molecules*** (*e.g.*, drugs and growth factors)
- Steps to model the clinical problem to guide the selection of the tools: "unit cell processes"
- Consideration of design features that will enable patient access globally, including resource-challenged settings
- FDA regulations of Class III medical devices
- Intellectual property and pathway to a ***Startup***

Prior Projects



Application of **EndoGuard**: prevention of post-surgical recurrence of superficial peritoneal endometriosis and fibrosis.
P Chacko, J Komen, J Lee, A Seabold. 2023



Endobronchial drug-eluting hydrogel for the healing of asthmatic patients who have undergone bronchial thermoplasty.
A Orji, B Schelhaas, J Xu, CA Luna. 2020

GRADING

The final grade will be based on:

- 20% QUIZ (Written)
- 20% Oral Progress Report/Oral QUIZ
  - 10% for Team performance
  - 10% for the individual Oral QUIZ
- 10% FDA Report (Written)
- 25% Final Oral Presentation
- 25% Final Written Report

PREREQUISITES

Prerequisites are the three Institute requirements in chemistry, biology and physics.

TASKS

The tasks highlighted in yellow are the graded items noted above in GRADING.

	Task	Due Date
1	Each student offers for discussion 1-3 options for design topic, and background/interests due	Feb 10
2	QUIZ (Written)	Mar 5
3	Finalize selection of design project and team members	Mar 10
4	Oral Progress Report and Oral QUIZ	Mar 31,Apr 2
5	FDA Report due	Apr 30
6	Final Written Report due	May 7
7	Final Oral Presentation	May 12

DESIGN PROJECTS

The design topic will be determined by the students. Each team will work on a separate problem.

Students will work in teams of 3 people. All individuals in the group will receive the same grade for the FDA Report, the Final Oral Presentation, and the Written Design Report.

In addition to being novel, the design needs to be realistic and well-rationalized with documented peer-reviewed references supporting the engineering basis for the design; the device needs to have a reasonable expectation for success.

The device will not be fabricated. However, detailed drawings of the device (with all biomaterials identified) and its location in the body are required. Some teams in prior years have patented their designs and took steps for commercialization.

The Instructors will allocate "consulting" time to each group.

COLLABORATION AMONG STUDENTS

The Written Quiz on March 6 does not permit collaboration among students.

Following the team PowerPoint presentation of the Oral Progress Report (on Mar 31 and Apr 2), the Instructors will quiz team members individually on their knowledge of their evolving design process. Students will answer with no input from other team members.

The FDA Report, final Oral Presentation, and the final Written Design Report require collaboration among members of a team.

GUIDELINES FOR TEAM CONSULTING WITH INSTRUCTORS

Candidate projects will be discussed in class until the March 10 deadline for the declaration of the membership of teams and the respective design topics; teams can be formed before that date and can begin meeting in their own group sessions.

After March 10, teams will meet separately in consulting sessions with the Instructors outside of class, with the following guidelines:

1. Prior to the Oral Progress Report, teams should meet with Instructors, for a total of at least 30 minutes per team per Instructor. Because the two Instructors have had different experiences in the medical device area, we are asking that the teams meet with each of them. Teams will initiate and arrange meetings with Instructors (please use e-mail). Teams should bring specific questions to the consulting sessions.
2. After the Progress Reports have been submitted and 1 week before the Final Oral Presentations, teams should continue to meet with both Instructors as needed or requested by the Instructor.

QUIZ (WRITTEN)

Quiz questions will be drawn from the lectures, related to the principles and practice of medical device design. The 90-min quiz will allow open use of notes and the Canvas website.

ORAL PROGRESS REPORT/ORAL QUIZ

The oral PowerPoint presentation is to be 12 minutes in length, with all members of the team participating in the presentation. The presentation is to define the clinical problem to be addressed by the device, and the current methods of treatment. The rationale and novelty of the team's approach for the device design need to be presented. Alternative strategies for the design are acceptable at this stage.

Following the 12-min presentation, the Instructors will direct questions to each team member individually for up to 3 min. per member, and grade their responses. The questions could be drawn from topics presented in the lectures, as they relate to the design. Questions also could deal with: the basic scientific principle/phenomenon on which the design is based; the biology of relevant wound healing/regeneration processes; the chemical formulation of the device; and/or relevant mechanics and materials science. Each student will receive a separate grade.

FDA REPORT

One report is to be prepared by each team, dealing with the regulatory issues attendant to the device. The issues related to FDA regulation of medical devices will be presented in 2 class lectures, March 10 and 12. The device design used for the FDA Report will not necessarily be the final design. All members of the team will receive the same grade. Total length is 8 pages, $1^1/_2$ line spacing and Times New Roman 12 or equivalent font; this includes text, all images and references. An outline for the FDA Report is on the Canvas website in the module, "INFORMATION ABOUT THE SUBJECT."

FINAL WRITTEN REPORT

The final written report is limited to 10 pages of text; figures and references are not counted in this 10-page limit; $1^1/_2$ line spacing and Times New Roman 12 or equivalent font.

Citation needs to be provided for the source of text that has been copied and pasted into the Report; such text needs to be placed in quotation marks if the wording has not been changed. This includes journal references and AI sources.

FINAL ORAL PRESENTATION

The final oral PowerPoint presentation is to be 12 minutes in length, with all members of the team participating in the presentation. It will be graded by a Panel comprising the 2 Instructors and 4 other individuals (faculty and other professionals) with experience with various aspects of medical devices. Details of the content and mechanics of the presentation will be discussed in class. The presentation will be followed by questions from the members of the Panel.

READING MATERIALS

- Readings posted on the Canvas class website

CONFIDENTIALITY

Content of the design project should be maintained confidential in the event that patent disclosures are to be submitted. Student discussions and presentations of their projects in the classroom do not constitute public disclosure, and therefore, will not jeopardize the filing of patent disclosures.

RELIGIOUS OBSERVANCES

In accordance with the Institute's Nondiscrimination Policy, please let Prof. Spector know if an assignment, exam, or class falls on the same day as an observance of your faith. Accommodation will be arranged.

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Lec	Date	Read		Lecturer[2]
I. PRINCIPLES OF IMPLANT DESIGN; TARGETS FOR TREATMENT; BIOACTIVE AGENTS				
1	Feb 3	1[1]	Design of Medical Devices Overview	Spector
2	5	2	Steps in the Design Process	Spector
3	10	2	**1-3 options for design topic; student background/interests** Make-up of Tissues/Organs	Spector/Liu Spector
4	12	3	Unit Cell Processes (UCPs): Wound Healing, Response to Permanent Implants	Spector
	17		**HOLIDAY: Presidents' Day**	
5	19	4	UCPs in Repair and Fibrotic Conditions: Treatment Targets	Spector
6	24	5	UCPs Underlying Regenerative Devices I. Overview/Biomaterials	Spector
7	26	6	Regen Dev II. Biomaterials + Regulatory Molecules	Spector
8	Mar 3	7	Regen Dev III. Biomaterials + Cells (Mitochondria, Secretomes)	Spector
9	5		**QUIZ (Written)**	
II FEDERAL REGULATION OF MEDICAL DEVICES				
10	10	8	Federal Regulation of Devices I Background and Classification **Finalize selection of design project and team members**	Spector Spector/Liu
11	12	8	Federal Reg of Devices II Biocompatibility, Clinical Trials	Spector
III. MEDICAL PROBLEMS AND THEIR SOLUTIONS				
12	17		Mechanical Augmentation of Organ/System Function	TBN
13	19	9	Musculoskeletal Problems: **Ligaments**, **Tendons**, **Cartilages**	Spector
	24		**HOLIDAY: Spring Break**	
	26		**HOLIDAY: Spring Break**	
14	31		**Oral Progress Report/QUIZ (Oral)**	Spector
15	Apr 2		**Oral Progress Report/QUIZ (Oral)**	Spector
16	7	10	**Dental/Maxillofacial** Problems and Treatments	Spector
17	9	11,12	Devices for ***Skin*** and ***Peripheral Nerve*** Regeneration	Spector
18	14	13	Tissue-Engineered ***Blood Vessels***	Dahl
19	16	14	Devices to Treat ***Cardiac*** Problems	Friehs
20	21	15	Approaches to Treat ***Spinal Cord*** Injury	Spector
21	23	16	Devices for Disorders in the ***Brain*** (Stroke)	Love
22	28	17	Injectable Gel Incorporating Photoreceptor Cells for ***Retinal*** Disease	Dromel/Singh
23	30	17	Whole Eye Transplantation; **FDA REPORT Due**	Alexander-Katz
IV. COMMERCIALIZATION OF MEDICAL DEVICES				
24	May 5	18	Steps to Startup and Funding	Spector
25	7	19	Intellectual Property **WRITTEN DESIGN REPORT due**	Van Eman
26	12		**Final ORAL PRESENTATIONS (11:00 AM-1:00 PM)**	Mock FDA Panel

1 **Readings**: Canvas website chapters

2 **Lecturers**

Myron Spector, PhD
Professor Emeritus Orthopedic Surgery
(Biomaterials), Harvard Medical School
Affiliate, MIT

Shannon Dahl, PhD
CARVE BIO LLC
CEO & Founder

Ingeborg Friehs, MD
Instructor in Surgery, Harvard Medical School
Department of Cardiac Surgery
Boston Children's Hospital

Christopher Love, PhD
Clinical Research Scientist
Viz.ai Remote
MIT MechE PhD (2020)

Pierre Dromel, PhD
CTO InGel Therapeutics (Co-founder)
MIT DMSE/PPSM PhD (2021)

Deepti Singh, PhD
CSO InGel Therapeutics (Co-founder)

Alfredo Alexander-Katz, PhD
Michael and Sonja Koerner Professor
Professor of Materials Science and Engr

Matt Van Eman, MD, JD
Partner
McCarter & English