

**ENGINEERING DESIGN CHALLENGE:
BIOMEDICAL ENGINEERING DESIGN
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Scenario

Dr. Mordecai Fleam, the president of Ermine Biomedical Solutions (EBS), has asked your class to develop new products involving the fixation of broken arms. In general, the medical solution to this injury is some sort of fixation, either external (such as a cast or a splint) or internal (such as a stainless steel plate). Since EBS already has a product line for internal fixation, Dr. Fleam would like to expand EBS's product line into the external fixation market. They have asked your class to develop a line of prototypes for their consideration.

- The class will be broken into teams of 3-4 students, with each team generating a potential product. Team projects can fall into one of three categories.
- Improve an existing product (e.g. a new material for the cast)
- Develop a product that makes living with a cast better (e.g. an arm scratcher for inside the cast)
- Develop a product to improve the survivability of the existing designs

Ermine Biomedical will provide a test "arm" for you to use in the development process. This arm has a built in break that you will have to immobilize with your device.

Since your class will be acting as consultants, EBS has requested that you follow the 7-stage engineering design process and document your process as you go in your design notebooks. In addition, you will need to write a short memo to Dr. Fleam every Friday to keep him informed of your progress. At the end of the project, you will present Dr. Fleam with a your design portfolio.

Goals and Outcomes

The overall emphasis in this case study is the engineering design process. This process will be explained using the example of a biomedical engineering problem, a product to be used with broken arms.

- a) Identification of the qualities of a good design
 - i) Students will be asked to identify the general qualities of good design.
 - ii) Students will be asked to identify how these qualities are applied to their design.
- b) Develop an understanding of the engineering design process
 - i) Students will follow a 7-stage engineering design process
 - ii) Students will document their design process in a design notebook
 - iii) Students will be asked to reflect on each stage of the design process and as a final step will be asked to evaluate their process and recommend improvements

- c) Understanding of the relationship between humans and engineering devices.
- i) Students will be exposed to medical product design including factor such as comfort, usability, and durability.
 - ii) Students will relate personal and associates experience to the development of engineering design criteria.
 - iii) Students will be exposed to the wound healing process.

Discussion of Constraints (Limits)

Before beginning the design, discuss the qualities of good design. The students will need to create a list of the qualities of good design, in general, and how they apply to this projects specifically. A partial list of good qualities is listed below.

- *Functionality – Does the device perform the desired function? Does it fit inside the cast? Does it provide relief from the itch?*
- *Quality – Is the device of an appropriate quality? Does it look good? Can you produce it repeatable? Will it last as long as the user is in the cast?*
- *Safety – Is the device safe to use? This includes use in unexpected way or by someone who is poorly trained? Ask your students to consider the items in the classroom that they have used in an unexpected way (e.g. using a pencil to scratch an itch that they cannot reach). Children possess most of the broken arms. How would these factors alter their design?*
- *Ergonomics (user friendly). – Does the device fit into the available space? Is it easy to hold and use? Is it comfortable to use?*
- *Appearance – Does it look attractive? Does it look well made? Would you want one?*
- *Environmental Considerations – Is you device made using an environmentally safe process? Everything that you purchase will one day be thrown away. Is your device recyclable?*
- *Societally Appropriate – Does the design match the audience? A design that is appropriate for a 5 year old may look silly when used by a grandmother. A design for vegetarians shouldn't have a leather strap.*
- *Economics – Can people afford to buy it? Can we afford to build it? Can we afford to sell it for a reasonable price and still make a profit?*
- *Manufacturability and Maintainability – Can we build it with the equipment and materials that are available? Can it be fixed if it breaks?*

Rank these qualities in order of importance. The designers need to understand that some of these qualities are more important than others. Some qualities of good design, in general, may not be relevant to this design, in particular. In addition, some qualities will act in opposition to each other. For example, increasing the durability of a cast may make it harder to remove when the arm is healed. Alternately, improving the appearance of a cast is likely to make it more expensive.

Social/Cultural Context

Biomedical engineering is one of the fastest growing engineering disciplines. With America's population aging its medical needs will continue to grow. Biomedical engineers need to consider, not just engineering design requirements, but also the relationship that their design will have with the human body.

Virtually everyone either has broken a bone or knows someone who has done so, usually involving a quick trip to the emergency room. In children, 40 -50% of all fractures involve the forearm. Fortunately, children's bones heal more quickly than the bones of an adult.

General Classroom Guidelines

This case study is aimed at teaching engineering design as a process. As such, the emphasis is on fostering creativity and structured methodology. The case study is specifically *not* to have a single outcome. Instead the design teams should be given maximum freedom in their solutions. The design constraints are in the attached letter from the fabricated "Dr. Fleam" from "Ermine Biomedical Systems."

No special facility requirements are needed to complete this engineering challenge. Passing the general safety test and other equipment-specific safety tests is required for participation in the research and development process and in the implementation part of the assignment. Materials safety data sheets should be available for all materials used in this case study.

It is estimated that this engineering challenge would take fifteen, fifty-minute class periods to complete.

Key Engineering Concepts

The key technological concepts that an engineering design team should be familiar with during and at the completion of this engineering challenge consist of:

- Standard 8. Students will develop an understanding of the attributes of design.
- Standard 9. Students will develop an understanding of engineering design.
- Standard 10. Students will develop an understanding of the role of troubleshooting, research and development, invention and innovation, and experimentation in problem solving.
- Standard 11. Students will develop abilities to apply the design process.
- Standard 13. Students will develop abilities to assess the impact of products and systems.
- Standard 14. Students will develop an understanding of and be able to select and use medical technologies.

Key Mathematics/Science Tools and Concepts

National Science Content Standards

Science and Technology – Content Standard E:

As a result of activities in grades 5-8, all students should develop:

- Abilities of technological design

- Understandings about science and technology

As a result of their activities in grades 9-12, all students should develop:

- Abilities of technological design

Science in Personal and Social Perspectives – Content Standard F:

As a result of activities in grades 5-8, all students should develop an understanding of:

- Personal health
- Natural hazards
- Risks and benefits

As a result of their activities in grades 9-12, all students should develop understanding of:

- Personal and community health
- Natural and human-induced hazards

Assessment

See Attached Rubric

Reflective Analysis

Engineering design is both a team activity and an inherently recursive process. Virtually every item that we see has gone through many design cycles. In each cycle, the design is improved and the design process gets better. Reflect on the process that has just been completed, examining the following three elements:

- People
- Process
- Product

As a team, write a reflective analysis of the engineering design process. Specifically, examine the roles and challenges for each of the above elements. This reflection should answer the following questions:

- What did we do right? (How do we do it again?)
- What did we do wrong? (How do we stop from making the same mistake again?)
- Examining the above questions, how can we improve what we did?

Biomedical Engineering and Biomaterials Evaluation Rubric

Objectives	Below Standard	At Standard	Above Standard	Specific Comments
Understands and is capable of identifying good design	There were one or more important criteria for good design omitted	There is evidence that the product met the criteria for good design	There is explicit evidence that the product met the criteria for good design	
Followed the engineering design process.	There were steps left out that turned out to be important.	There is evidence that the process was followed.	There is explicit evidence that the process was followed.	
Identified and met the design constraints and limitations	One or more special accommodation had to be made in the laboratory to get the solution to work.	No special accommodation had to be made in the laboratory to get the solution to work.	The solution worked as close to a real-life implementation as feasible in the laboratory.	
Performed appropriate background research	Little or no background research is evident in the memos and design portfolio	Background research is evident in the memos and design portfolio	Extensive background research is evident in the memos and design portfolio	
Understands the role of and methods for brainstorming	Minimal evidence is present of brainstorming/ evidence exists of counterproductive activity	Evidence is present of brainstorming/ no evidence exists of counterproductive activity	Evidence is present of extensive brainstorming and this is explicitly documented in the portfolio.	
Analyzes and refines potential solutions	Minimal evidence is present of the analysis and refinement of the potential designs	Evidence is present of the analysis and refinement of the potential designs	Evidence is present of the analysis and refinement of the potential designs and this is explicitly documented in the portfolio.	
Creates and examines multiple solutions for the design	There is little evidence that multiple solutions were considered.	It is evident that multiple solutions were considered..	It is evident that multiple solutions were considered. and this is explicitly documented in the portfolio.	
Develops and tests models for design	Test model of a single design is presented	Test models of 2-3 designs are presented	Test models of 2-3 designs are presented and this is explicitly documented in the portfolio.	
Ability to impartially examine multiple designs and choose a design to finalize.	There is little evidence of an ability to examine multiple designs and choose a design to finalize using a decision table.	It is evident that multiple designs were examined in the process of choosing a design to finalize. A decision table was used.	It is evident that multiple designs were examined in the process of choosing a design to finalize. A decision table was used is explicitly documented in the portfolio.	
A final design choice was made and an example of the product was generated	No design choice was made and an example of the product was not generated.	A design choice was made and an example of the product was generated.	A design choice was made and an example of the product was generated. The product is well made and documented.	
Understands the need for and is able to communicate their design	The student cannot describe the design and their current status in the design process.	The student can describe the design and their current status in the design process	The student can describe the design and their current status in the design process and this is evident in the memos and design portfolio.	
Fully documented the process in the portfolio.	The memos and portfolio reflect the general engineering design process.	The memos and portfolio provide evidence of understanding for the objectives stated above.	The memos and portfolio document the specific design process used to solve this problem.	

Objectives	Below Standard	At Standard	Above Standard	Specific Comments
Understanding of production requirements and intellectual property	Minimal evidence is present of production requirements and intellectual property	Evidence is present of production requirements and intellectual property	Evidence is present of production requirements and intellectual property and this is evident in the memos and design portfolio.	
Analysis of the engineering design process and product	Minimal evidence is present of reflection of the process	Evidence is present of a post-process reflection.	Evidence is present of a post-process reflection and recommendations are made for improvement of their process and design in their portfolio.	
Comments:				