YYSH/v6

EGT2
ENGINEERING TRIPOS PART IIA

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Monday 28 April 2025 9.30 to 11.10

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**Module 3G5**

**BIOMATERIALS**

*Answer not more than **three** questions.*

*All questions carry the same number of marks.*

*The **approximate** percentage of marks allocated to each part of a question is indicated in the right margin.*

*Write your candidate number **not** your name on the cover sheet.*

**STATIONERY REQUIREMENTS**
Single-sided script paper

**SPECIAL REQUIREMENTS TO BE SUPPLIED FOR THIS EXAM**
CUED approved calculator allowed
Engineering Data Book

**10 minutes reading time is allowed for this paper at the start of the exam.**

**You may not start to read the questions printed on the subsequent pages of this question paper until instructed to do so.**

**You may not remove any stationery from the Examination Room.**

1 (a) Briefly describe the structure of woven and lamellar bone. Explain when each type of bone would develop. [15%]

(b) State the main causes for hip replacement. [15%]

(c) Sketch and label the components used for hip replacement. Briefly describe the requirements for hip implants. In your answer, you should consider mechanical, biological, chemical and processing requirements. [25%]

(d) You have been contacted by an external consultant to assist in selecting a prosthetic implant for young active patients.

(i) Describe your chosen method of implant fixation. Explain the materials-selection criteria for the implant components and list the chosen materials. Discuss the surface treatments you would employ to facilitate the fixation of the implant to the surrounding bone, and the region they would be applied to. Explain your reasoning. [35%]

(ii) One of the consultants suggested that the main reason for hip implant failure is wear. Briefly comment on whether you agree with this suggestion. [10%]

2 A firm is designing a new active implantable medical device, called a neurostimulator. This is a device that is implanted in the skull to measure brain activity for identifying seizure events. Seizure detection then triggers the delivery of an electrical current to the tissue that stops the seizure. The firm plans on making and selling the device in the EU first and then expanding to the US in the future.

(a) The firm believes this is probably a Class III medical device under both EU and US regulations. Explain how they would confirm if this classification were correct in both cases. [15%]

(b) Explain what is meant by the term *biocompatible*, in relation to medical devices. [10%]

(c) Describe how the firm would ensure this new device is biocompatible. [20%]

(d) The firm must provide a sterilised, packaged product to their customers. The firm is going to try ethylene oxide and gamma radiation sterilisation techniques to test if they are suitable for their device. Describe any two benefits and any two challenges for each of these techniques. [20%]

(e) Describe any two trends in the medical devices market that may influence the design of this new technology. [20%]

(f) Explain how medical device regulations ensure safety throughout the lifespan of the device. [15%]

3 Many polymer-based biomaterials are subjected to hydrolysis as part of the biodegradation process.

(a) State what a hydrolysis reaction is. [5%]

(b) A new hydrolysable polymer is synthesised to be potentially used for localised delivery of cancer drugs. This new co-polymer was measured to exhibit a critical thickness ($W_c$) for bulk versus surface erosion of 1 mm.

(i) The hydrolysable polymer is made into a suture with a diameter of 300 μm. Sketch the likely delivery profiles for this suture, i.e. rate of drug release versus time, and total mass of drug release versus time. State your assumptions. [15%]

(ii) Based on (b)(i), suggest whether this drug releasing suture could be suitable for localised cancer drug delivery in the brain. Briefly state your reasoning. [10%]

(c) Both poly(lactic-co-glycolic acid) (PLGA) and collagen can be used as suture materials.

(i) Compare the hydrolysis reactions associated with a PLGA suture versus a collagen suture when interfaced with body fluids. You may support your answer with a sketch. [30%]

(ii) State how co-polymerisation affects the properties of a PLGA suture. You may support your answer with a sketch. [10%]

(d) For the following polymer characteristics, briefly discuss their effects on the rate of hydrolysis degradation of a hydrolysable polymer.

(i) Degree of crystallinity; [10%]

(ii) Molecular weight distribution; [10%]

(iii) Degree of polymerisation. [10%]

4 (a) Mechanical valve and biological valve are two different types of heart valve replacements.

(i) In a mechanical valve, state the material that is typically used for forming the flap structure which regulates blood flow. [10%]

(ii) The flap structure in a biological valve is currently made from sterilised, cell-free biological tissues. Discuss how the material properties associated with a biological tissue flap determine its performance and usage, as compared to a mechanical valve. [20%]

(iii) Ongoing research proposes to incorporate cells into the biological flap structure in order to produce a tissue engineered valve. Suggest the motivation behind this research proposal. Discuss major considerations associated with the cell component of such a tissue engineered valve. [30%]

(b) Describe the different states of water present in a hydrogel. [15%]

(c) In early designs of total hip implants, high-density polyethylene (HDPE) was commonly used as the plastic liner.

(i) What is the most likely degradation mechanism of a HDPE liner? State the consequences of such degradation on the implant host. [15%]

(ii) To upgrade the plastic liner material, a designer suggests replacing HDPE with polyurethane. Comment on the suitability of this upgrade. [10%]

**END OF PAPER**

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