Version YYSH/5

EGT2
ENGINEERING TRIPOS PART IIA

Monday 24 April 2023 9:30 to 11:10

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) Bone is composed of a mineral and a non-mineral component. Name the components and describe how they are arranged at the nano and micrometer scales in the human femur. Briefly also describe the bone structure and main features at the millimetre scale. [20%]

(b) Bone is a responsive material; explain what is meant by this term and give an example which demonstrates this behaviour. Explain this behaviour in the context of Wolff's law. [20%]

(c) Sketch and label the components used in total hip replacement. List the materials used in the femoral head. Indicate their advantages and disadvantages. [20%]

(d) Describe, giving reasons for your answers, the choice of the method of hip implant fixation that you would make for (i) a young patient and (ii) an elderly patient. What are the advantages and disadvantages of these methods of fixation? [25%]

(e) Briefly describe two porous coatings used on the stems of hip prostheses, explaining their functions. [15%]

2 (a) The Medical Devices Directive and In Vitro Medical Devices Directive were introduced to Europe in 1993 and 1998 respectively to ensure devices would only be placed on the market if they did not compromise the safety and health of users. These Directives introduced the concepts of:

- Classification.
- Monitoring of devices and adverse events in-use.
- Clinical data requirements.

(i) Explain what is meant by each concept and include in your answer a note about the role of the manufacturer in each case. [20%]

(ii) For any two of the concepts above, describe the changes introduced with the new Regulations in 2017. [20%]

(iii) Describe any one area where you feel medical device regulations need to be further developed in the future and explain why. [10%]

(b) Joint pain from osteoarthritis occurs when the protective cushioning layer in joints wears down. A new porous nanocarbon/polymer composite material is being researched that could be surgically implanted into joints to slowly release a lubricating fluid over time.

(i) Describe any two considerations linked to bioethics when researchers are designing a clinical trial or recruiting participants to test these new implants. [20%]

(ii) Apart from clinical trials, describe any two other sets of tests that will need to be arranged as the team brings this medical device to market. In each case, explain what is being tested and note what problems could cause these devices to fail the named tests. [30%]

3 Polymers are used extensively in biomedical applications.

(a) A synthetic polymer has a molecular weight distribution as shown in the table below. Calculate the number average molecular weight (M_n), weight average molecular weight (M_w) and polydispersity index (PI). [20%]

Chain molecular weight (kDa)	20	60	100	120	140
Number of chains at the specified molecular weight	50	300	800	350	100

(b) Suggest a suitable synthetic polymer for each of the following applications, and explain your choice. For applications (i) and (ii), comment on how the molecular weight of your selected polymer could affect the application scenario.

(i) An attachment on drug carriers to slow down the carriers' clearance from blood, [20%]

(ii) An acetabular liner in the total hip replacement, [20%]

(iii) A suture in the cornea, [15%]

(iv) A hydrolysable drug delivery carrier. [15%]

(c) Give an example biomedical application of fibrin, and briefly state its formation mechanism. [10%]

4 (a) Collagen is the main structural protein in the extracellular matrix found in the body's various connective tissues.

(i) Describe the secondary, tertiary, and quaternary molecular structures of collagen. You may include sketches to aid your answers. [20%]

(ii) Give two examples on how process treatments affect the molecular structure of collagen. For each example, discuss how the associated process treatment affects the resultant mechanical and biochemical properties, and thus the biomedical applications of the collagen-derived biomaterial. [25%]

(b) A drug clears the body by exponential decay with a half-life of 2 hours. It has a minimum effective dose of M_{min}, and a toxic dose of $4M_{\text{min}}$.

(i) The drug can be delivered by injections and is assumed to be instantaneously released at the time of delivery. Design a multiple injection profile model which maximises the time interval between injections. What is the average drug dose accumulated in the body system? [20%]

(ii) Design a controlled release mechanism that will result in a steady state drug accumulation dose of $3M_{\text{min}}$. Suggest a suitable type of delivery device to achieve such a controlled release. [15%]

(c) What is a biofilm? Give two examples on how biofilm formation can cause implant failure. [20%]

END OF PAPER

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