Version YYSH/6

EGT2
ENGINEERING TRIPOS PART IIA

Monday 22 April 2024 9.30-11.10

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) Describe the balloon angioplasty procedure and how the outcome of this procedure relates to stenting. [15%]

(b) Classify stents on the basis of the method of expansion. Describe briefly the procedure involved and state the mechanism responsible for their expansion. Explain how strut members should be oriented to facilitate stent delivery. Explain your reasoning. [25%]

(c) Explain what is common between superelasticity and shape memory effects and the conditions that must be satisfied for these effects to take place. Describe how superelasticity is exploited in stents, illustrating your answer with sketches. Which effect, superelasticity or shape memory, would you consider more suitable for a cardiovascular stent. Give reasons for your choice. [40%]

(d) What are the short- and long-term complications of stenting? List four surface treatments used to address some of these complications. Briefly describe one such treatment, explaining its function. [20%]

2 (a) A firm is developing a long-term implantable medical device for the delivery of insulin. It uses data about the patient gathered from a wearable sensor on their wrist and machine learning to then instruct the device to deliver the optimum amount of insulin when needed.

(i) Describe any one challenge the firm may face when trying to identify a classification for their device. [10%]

(ii) Describe any three additional challenges that would be faced when trying to gain regulatory approval for this device. [30%]

(b) A hospital is trying to reduce costs and has asked clinicians to start re-using medical devices within the hospital where it is safe and legal to do so. Describe any four challenges you anticipate will be faced by the hospital to implement this new approach. Use examples of specific medical devices to support your answer. [30%]

(c) When sterilising a medical device and ensuring it is free of all living organisms, the time the device is exposed to the sterilising environment is an important parameter.

(i) Explain how you would determine the required time a device undergoes a given sterilisation technique to ensure it meets regulatory approval. [20%]

(ii) Give examples of four other process parameters that can be important to control during sterilisation, noting the sterilisation techniques where each parameter is relevant. [10%]

3 (a) The examples below show biomaterial applications, each with two possible material choices. For each application, discuss how biocompatibility and material selection considerations could be context dependent.

(i) Heart valve flap: Cell-free biological tissue *versus* Pyrolite® Carbon. [20%]

(ii) Suture: Poly (lactic-co-glycolic acid) (PLGA 90/10) *versus* nylon. [20%]

(b) Poly(2-hydroxyethyl methacrylate) (pHEMA) hydrogel and Polymethyl methacrylate (PMMA) are both possible materials for contact lenses.

(i) How does the degree of polymerisation affect the strength and elongation to failure of PMMA. Use sketch(es) to illustrate your answer. [15%]

(ii) Discuss how the degree of crosslinking could affect the nominal tensile stress-strain curve of pHEMA hydrogel. Use sketch(es) to aid your answer. [20%]

(iii) On the same plot, sketch the nominal tensile stress-strain curves to failure for pHEMA hydrogel and PMMA. Label key features on the plot. Hence comment on their potential for use as contact lens materials. [25%]

4 (a) Bacterial infection and biofilm formation can lead to medical device failure.

(i) Describe the five stages of biofilm formation. You can use schematic(s) to aid your answer. [20%]

(ii) Which of the following medical devices is more likely to have the highest rate of infection during clinical deployment? [10%]

A. Vascular grafts;
B. Fracture fixation devices;
C. Mechanical heart valves.

(iii) Which of the following biological factors are key to the human's immune response to bacterial infection? Select all that apply. [10%]

A. Complement proteins
B. Fibrinogen
C. Leukocytes
D. Fibroblasts
E. Collagen

(b) Tissue engineering applies the principles of engineering and life sciences toward the development of biological substitutes that restore, maintain, or improve function of an organ.

(i) State why a tissue engineered heart valve can be of particular importance for a child recipient. [15%]

(ii) Describe three strategies for the vascularisation of a thick tissue engineered construct. [30%]

(c) Cellulose can be produced in large quantities by some bacteria strains grown in laboratory culture. Discuss potential complications of using bacterial cellulose for wound dressing applications. [15%]

END OF PAPER

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