Version YYSH/5

EGT2
ENGINEERING TRIPOS PART IIA

Monday 27 April 2026 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) Explain the function of a cardiovascular stent. Briefly describe the two types of stents based on their method of expansion. In each case, state the mechanism responsible. [25%]

(b) Define martensitic phase transformations in the context of superelasticity and shape memory effects. Use sketches to illustrate your answer and explain the key characteristics that allow this transformation to occur, including why it is rapid and reversible. [25%]

(c) Figure 1 shows the predicted dependence of the Young's modulus along the long axis of a stent (axial Young's modulus) on the strut orientation angle, θ, for two stent designs: (i) a single-angle ply, and (ii) a $\pm\theta$ angle ply. Identify the optimum range of strut orientation angles and suggest which of the two stent designs would be more suitable for use. Justify your answer. Explain why the axial Young's modulus is important in preventing Neointimal Hyperplasia. [25%]

(d) Explain why drug-eluting coatings are developed. Briefly describe how they work and list their main potential advantages. [15%]

(e) Explain the motivation for developing biodegradable drug-eluting stents as alternatives to drug-eluting metallic stents. From a mechanical perspective, what do you consider to be the greatest challenge in their design? [10%]

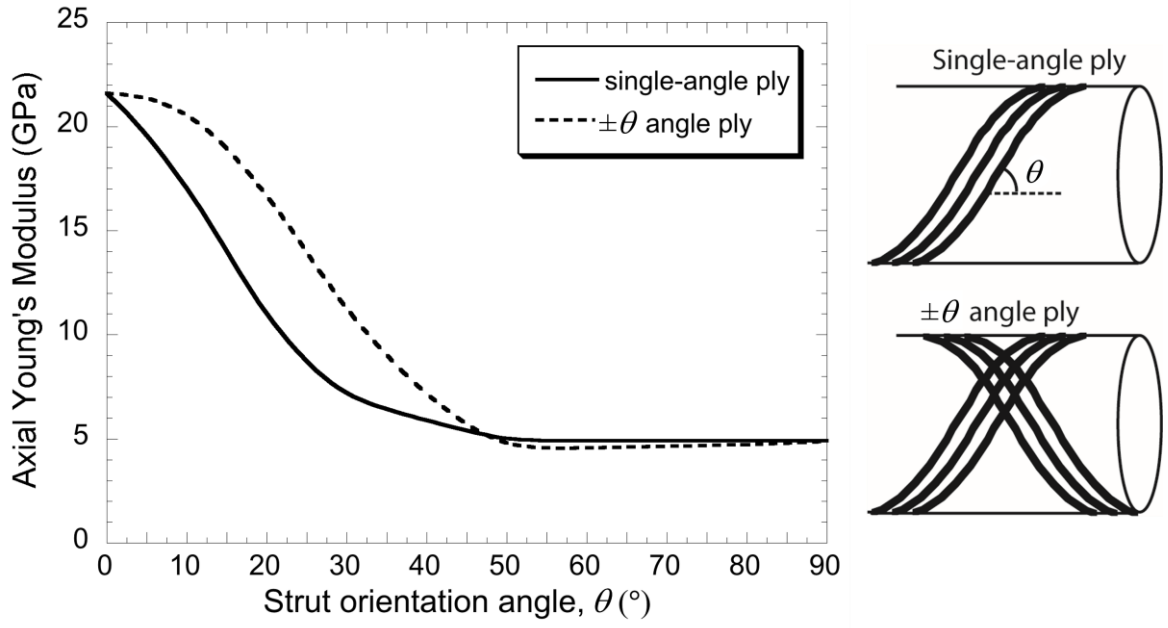

Fig. 1

2 (a) A company is developing a new, wearable Class II medical device. It is a very thin, flexible wristband that can monitor a patient's location in a hospital, their heart rate, blood pressure, blood-oxygen levels, and quality of sleep. This new device is designed to be light and flexible so it is comfortable for a patient to wear all the time. The band is made from a flexible polymer, and the embedded electronics and sensors are made using lithography, to create ultra-small sensors and wireless communication. The company plans on collecting the used bands from hospitals every month, re-sterilising them, testing them and, if satisfactory, re-packaging and selling them back to hospitals at a discount.

(i) Explain what is meant by the term *International Standard*. [10%]

(ii) Describe 3 examples of when *International Standards* would be used by the company as they develop this wearable medical device. [15%]

(iii) Explain how this company would decide which sterilisation technique would be most appropriate for use with their medical device. [20%]

(b) (i) Explain what is meant by the term *Bioethics*. [10%]

(ii) Explain what is meant by the term 'consent' in relation to *Bioethics* and why it is important when developing a new medical device. [10%]

(c) (i) Describe any 4 differences between the EU and US regulatory processes when seeking approval for a new medical device. [20%]

(ii) Explain any benefits if the EU and US moved to a single, agreed regulatory process. [15%]

3 (a) Gelatine–methacrylate (GelMA) is gelatine modified with methacrylate groups, enabling chemical crosslinking via free-radical polymerisation, while retaining the key biochemical properties of gelatine.

(i) How do each of the following factors affect the modulus, tear strength, and elongation to break of a fully crosslinked GelMA hydrogel? Support your answer with appropriately labelled plots.

- Molecular weight of gelatine;
- Degree of methacrylate group modification on gelatine;
- Concentration of gelatine in the hydrogel. [30%]

(ii) Compare and contrast the key physical, structural and biochemical characteristics of a GelMA hydrogel and a freeze-dried GelMA sponge. For each form of GelMA, propose a potential application and briefly justify your choice. [25%]

(b) Implantable subcutaneous glucose sensors are subject to in vivo performance degradation and require periodic replacement, typically every 7–14 days. Describe the sequence of events at the biomaterial–tissue interface that can alter the sensor performance in this period. [35%]

(c) List three main degradation mechanisms of a collagen-based vascular graft in vivo. [10%]

4 Polymer carriers loaded with therapeutics enable controlled release of a drug by controlling factors such as drug diffusion and degradation of the carrier.

(a) In a diffusion-controlled device with a reservoir and membrane format, illustrate the conditions of the device when a constant rate of release is achieved. Support your answer with appropriately defined and clearly labelled sketches. [25%]

(b) In a chemically controlled device, polyester copolymers can be designed to encapsulate drugs and enable controlled release through hydrolysis-driven polymer erosion.

(i) A polyester copolymer exhibits a critical thickness W_c = 500 μm separating surface versus bulk erosion behaviours. For mouth ulcer treatment, the copolymer is made into a film for drug delivery in the mouth. Sketch likely release profiles (i.e. rate of drug release, and total mass of drug released over time) for films of thicknesses 100 μm and 2 mm. State your assumptions. [20%]

(ii) How do each of the following modifications to the polyester copolymer alter the critical thickness, and the associated release profiles of a 2 mm film? Briefly justify your answer.

- Increased hydrophilicity of the side-chains;
- Increased polydispersity index while maintaining the same weight average molecular weight of the copolymer. [35%]

(c) Describe the working principle of an osmotic controlled device, and compare its performance with a reservoir and membrane diffusion-controlled device. Support your answer with a sketch. [20%]

END OF PAPER

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