Version AEM/2

EGT2
ENGINEERING TRIPOS PART IIA

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5 May 2017 9.30 to 11

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.

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

1 (a) Describe the biological events that occur at a biomaterial surface during the first few weeks following its implantation at a site where blood vessels have been damaged. [60%]

(b) Tissue engineered constructs using biomaterials seeded with cells *in vitro* prior to implantation offer a solution to treat damaged tissues or organs. Discuss the strengths and limitations of this approach. [40%]

2 (a) (i) Explain how shape memory and superelastic endovascular stents are deployed. Describe the shape memory effect illustrating your answers with sketches. What advantages does a shape memory stent have over a balloon expandable stent in terms of its delivery? [35%]

(ii) What are the main complications of stenting? Explain how drug-eluting coatings can address some of these complications. Hence explain how such coatings function. List their potential advantages. [20%]

(b) List the materials used for the femoral stem and head. In cases where different classes of materials could be used for the same component, indicate their advantages and disadvantages. Describe, giving reasons for your answers, the choice of method for hip implant fixation that you would make for (i) an elderly patient and (ii) a younger patient. Describe the advantages and disadvantages of these fixation methods. [45%]

3. Silicone elastomers have a network structure based on cross-linked polydimethylsiloxane (PDMS) chains. Figure 1 shows the repeated unit of PDMS, and a plot showing experimental data of the Young's modulus of a commercial silicone elastomer as a function of the percentage of crosslinking.

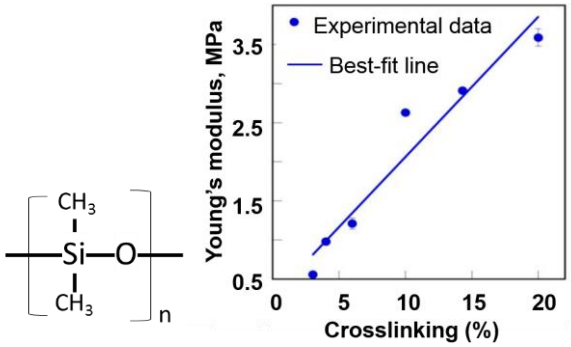

Fig. 1

(i) The manufacturer's datasheet states that the PDMS has a number average molecular weight M_n of 72,000 g mol^{-1}. Estimate the number of repeated units n. How does your estimated n value compare to those of the entire polymer population of the product? [20%]

(ii) Sketch network structures with a low and a high number of cross-links. Explain using your sketch, what is the average molecular weight of the network chain M_C. [15%]

(iii) The Young's modulus E of an elastomer network is given by the following rubber elasticity equation

$$E = \frac{3\rho RT}{M_C}$$

where ρ is the elastomer density, R the ideal gas constant and T is the temperature. Explain how this equation can account for the dependence of the Young's modulus on the amount of crosslinking. Hence, estimate the upper and the lower limits of the Young's modulus of the PDMS product above. [35%]

(iv) State the condition(s) for the rubber elasticity equation to be valid. Using your results in (iii), explain the trend of the data presented in Fig. 1. Comment on the Young's modulus values shown in Fig. 1 with respect to the estimated upper and lower limits in (iii). [15%]

(v) Briefly comment on PDMS's suitability for use as skin graft and bone graft. [15%]

[ρ = 1 g cm^{-3}, R = 8.3 J mol^{-1} K^{-1} and T = 300K.
Relative atomic weights: Si = 28, C = 12, H = 1 and O = 16.]

4. (a) Controlled drug release can be achieved by dispersing the drugs homogeneously into a hydrolysable polymer matrix. When the polymer matrix is eroded, drugs are simultaneously released.

(i) List the factors that influence the rate of hydrolysis erosion. [20%]

(ii) Sketch the delivery profiles (i.e. rate of drug release, and total mass of drug released over time) of a drug patch undergoing bulk erosion and surface erosion. State your assumptions. [15%]

(iii) Suggest which of the two erosion mechanisms should be used for sustained drug release in a patch. What are the design considerations of the polymer matrix in order to achieve the desirable release profile? [15%]

(b) Your company designs and produces an arterial blood filter that is used in hospitals during cardiopulmonary bypass procedures. You need to ensure that the component provided is fully sterilised within a protective polymer pouch.

(i) Explain what is meant by "sterilisation" of medical devices. Include in your answers example techniques commonly used in industry for sterilisation and describe any one technique in detail. [10%]

(ii) Recent measurements of the sterilisation technique currently used by your company are shown in Table 1. The table shows a decrease in microorganisms detected with increased sterilisation time. Using these measurements, calculate the bioburden and also the sterilisation time you would recommend to ensure the Sterility Assurance Level of 10^{-6} is achieved, noting any assumptions you make. [20%]

(iii) Your company is considering moving from ethylene oxide sterilisation to gamma radiation sterilisation. List the factors that should be taken into account when considering such a change. [20%]

Sterilisation time (min)	**No. of microorganisms**
10	3×10^5
20	6.7×10^3
30	1.5×10^2

Table 1

END OF PAPER

Answers

3. (i) ~973, (iii) E_{lower}= ~100 kPa, E_{upper}= ~97 MPa

4. (b)(ii) 88-96 minutes.