Version YYSH/3

EGT2
ENGINEERING TRIPOS PART IIA

Monday 26 April 2021 9.00 to 10.40

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 and at the top of each answer sheet.*

STATIONERY REQUIREMENTS
Write on single-sided paper.

SPECIAL REQUIREMENTS TO BE SUPPLIED FOR THIS EXAM
CUED approved calculator allowed.
You are allowed access to the electronic version of the Engineering Data Books.

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

The time taken for scanning/uploading answers is 15 minutes.

Your script is to be uploaded as a single consolidated pdf containing all answers.

1 (a) List the materials commonly used in the components of the following three implants. In each case, explain the materials-selection criteria and describe the condition these implants are used to treat.

(i) hip implant; [15%]

(ii) endovascular stent; [15%]

(iii) endovascular stent graft. [15%]

(b) When referring to cell attachment, are orthopaedic implants and cardiovascular stents any different? Explain your reasoning. List the techniques typically employed to ensure that appropriate levels of cell attachment are achieved. [15%]

(c) Figure 1 shows part of the wall structure of the New Intra-vascular Rigid flex stent, in the unexpanded state, once it is "unwrapped" so that it is planar.

(i) Sketch the "unit cell" of the planar wall structure, with sides parallel to the axial and hoop directions, in the unexpanded state. Also sketch the same unit cell after optimal expansion of the stent. [25%]

(ii) Explain how this geometry facilitates insertion of the stent. [15%]

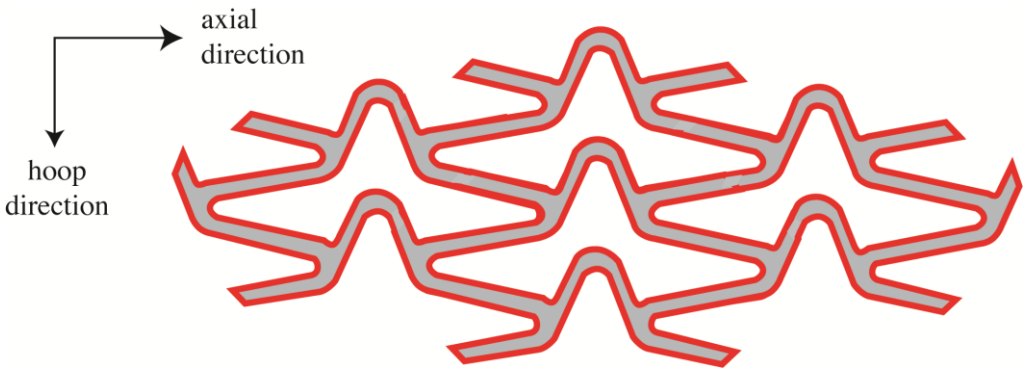

Figure 1. Wall structure of the New Intra-vascular Rigid flex stent before expansion.

2 A firm is developing an affordable delivery method for a coronavirus vaccine that can be rapidly manufactured at a large scale. The vaccine solution is contained as a complete dose inside a fully-disposable syringe and needle, as shown in Figure 2. The firm have developed a bulb as part of the syringe that can be squeezed to deliver the vaccine to the patient. The vaccine is purchased from a pharmaceutical company in the form of an aqueous solution containing the vaccine protein. The needle, cap and new plastic syringe design will be made by a third party. The manufacturing firm fills the vaccine, attaches the needle and seals the product within a plastic pouch, ready for packing and shipping.

(a) Describe in detail how you would identify an appropriate sterilisation technique for this product. [40%]

(b) The new type of syringe is a medical device and needs regulatory approval. Explain the role of international standards when preparing a device for approval. [20%]

(c) The firm is moving this year from following the old Medical Device Directive to following the new EU Medical Device Regulation. Describe briefly any three reasons why the new Medical Device Regulation was introduced in Europe and highlight any one additional consideration the company will have to take into account when manufacturing the device described above. [20%]

(d) The same firm is designing a rapid, affordable microfluidic biosensor so a physician can test a patient's blood sample for coronavirus antibodies. Describe any two benefits and two challenges to using microfluidics when designing this new test. [20%]

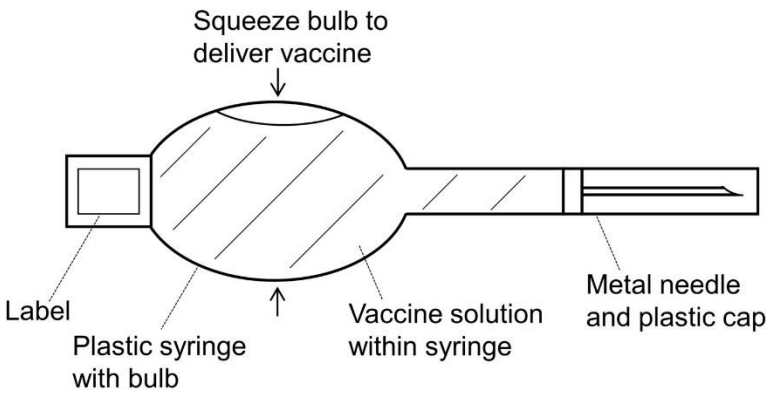

Figure 2. Affordable delivery product for coronavirus vaccine.

3 A list of polymers and their example biomaterial applications is shown below. For each biomaterial application: first, explain why a particular material is used, by considering the material's properties, forms, and functions; second, state the most probable *in vivo* degradation mechanisms (which could be intended or non-intended) of the biomaterial.

(i) Polyurethane for urinary catheter; [20%]

(ii) PGA (50%)/PLA (50%) PLGA co-polymer for drug delivery capsules; [20%]

(iii) Alginate hydrogel for cell delivery; [20%]

(iv) Fibrinogen/fibrin as a medical glue; [20%]

(v) Nylon for non-absorbable monofilament sutures used in cornea tissues. [20%]

4 (a) Diffusion controlled drug delivery devices have two typical device types: monolithic, and reservoir & membrane.

(i) Based on the scenario of a slab geometry, sketch and describe the configurations of drug loading for the two device types. [15%]

(ii) List the main factors that influence the rate of drug delivery for the two device types, with the geometry as stated in (i). [15%]

(b) List the main factors that influence the drug release profile of hydrolysable polymer capsules which undergo erosion triggered release. [20%]

(c) A drug, which clears the body by exponential decay with a half-life of 4 days, exhibits a toxic dose of 200 mg, and a minimum effective dose of 80 mg.

(i) Design a multiple injection profile model where each injection has a dose M_0 of 180mg. State your model assumption(s) and sketch the resultant delivery profile with appropriate labels reflecting key features. [20%]

(ii) Based on the multiple injection model you proposed in (i), what is the difference in approximate average mass of drug found in the recipient, for M_0=180 mg, compared to M_0=150 mg? [20%]

(d) In the context of an implantable medical device, briefly state how biological responses create obstacles to the function of a glucose sensor which is implanted under the skin. [10%]

END OF PAPER