Crib for MET1 3P10 2011

Section A

1 (a) An eco-audit is a simple life cycle analysis tool for assessing the environmental impact of a product, captured by a single measure such as energy consumption (or CO_2 emissions). It does not look at factors such as toxicity of materials. For an energy payback calculation, energy consumed in the lifecycle is clearly the required output. The system boundaries are to some extent pre-defined if a system such as CES is used to provide data, but always need to be considered explicitly. Material production energies, manufacturing process energies and transport are the main factors. In the 'use' phase, a contribution to electricity transmission infrastructure and maintenance could be included. Disposal at the end-of-life is less well-characterised, particularly for emerging products such as wind turbines, few of which have reached the end of their life.

Limitations of eco-audits include: uncertainty in setting system boundaries, inherent approximations in the input data (e.g. combining multiple parts transported from many suppliers by different means, and the accuracy of database values for energy/kg associated with a material or manufacturing process).

To conduct an eco-audit, two sets of input data are required. The user specifies: (a) the breakdown of the product into materials with their respective masses and manufacturing routes; (b) the types of transport used and distances involved in manufacture, installation and maintenance; (c) the duty cycle – energy consumption during use, and (in the context of energy-producing devices) the energy output over the product life. These are combined with standard data relating to each life stage (as in CES): (i) primary production energy (i.e. per kg of raw material – sometimes referred to as the *embodied energy*); (ii) manufacturing energy (e.g. again per kg of material, for forming, moulding, extrusion etc); (iii) typical transportation energies (per tonne, per kilometre); (iv) energy conversion efficiencies. Energies consumed and potentially recovered in the disposal stage can tentatively be included. The output is the energy (or CO_2) audit over the lifecycle, giving the total energy and the stage that dominates (usually materials for a product such as a wind turbine).

The amount of energy generated by the turbine will be estimated using local wind data to find a *capacity factor* – the fraction of the rated power output that is actually achieved, averaged over the year. This provides an estimated kWh (or Joules) of energy output per year. The payback period is then: total life cycle energy / energy produced per year.

(b) Environmental assessment of a company can involve very different criteria, depending on the purpose of the assessment. In this case, it could be prudent to include some mention of 'popular' metrics as well as the more significant truly environmental factors.

A good place to start is finding whether the company has been convicted of infringements of any standards of emissions (e.g. gaseous emissions or pollution of land or water).
The attention of the reporter could be drawn to some of the Sunday Times environmental competition criteria:

- Environment management system (EMS): an EMS that meets the ISO 14001 international standard
- Public reporting of green issues: green credentials subject to third-party verification
- Carbon footprint: companies which have calculated their carbon footprint
- Green training: evidence of environmental awareness in the factory (e.g. avoidance of waste of any resources)
- Electricity, gas and water consumption: signs of continuous improvement
- Waste management: signs of reduction in waste, including reduction in waste sent to landfill. Packaging is a particularly visible sign of this: are there signs of excessive packaging, or re-usable packaging?
- Information about suppliers and supply chains may be difficult to gain on a casual visit, but positive factors would be use of local suppliers, and a negative factor would be materials and components arriving by air freight from countries which are largely unregulated.

A company such as this, which must be aware of local opposition to its operations, may well be involved in the community. Whilst activities such as funding the local school sports day are pure greenwash, look out for activities which provide environmental education (e.g. educational factory tours).

Examiner's comments:

In part (a) most candidates could describe what an eco-audit was and discuss its limitations, though many went into detail on the non-energy impacts which are not part of a simple eco-audit, particularly if the goal is to find the life cycle energy to calculate an energy payback period. Few actually addressed the question "Explain how you would conduct an eco-audit...": answers were in general terms about "finding the impact of materials and transport", rather than stating what this calculation would actually *involve*: i.e. actual breakdown of components by material and mass, energy/kg data for materials, transport distance, energy/kg.km for different transport modes, and so on. Part (b) was well-answered, particularly so if presented as clear bullet points.

Section B

2 (a) (i) Instead of replacing defective tissues with man-made devices, try to re-grow healthy tissues by making living implants with active cells. From a biomaterials perspective the emphasis is on the scaffold material and its porosity, cell attachment capability, and biodegradability. Ideally cells in a TE device generate healthy ECM and this would fill in the gaps left by degradable materials as they eroded away! A tissue engineered implant will typically have the following components: biological cells and a scaffold to support the cells initially. It can also potentially contain a stimulatory chemical component (which can be coupled to the scaffold) such as signalling molecules or growth factors.

Autologous cells are those that come from the patient's own body. There are two advantages of this: one, there is no risk of immune rejection from the cells since the body would see them as "familiar" instead of "foreign"; two, there are no ethical quandaries associated with the use of the cells since they do not come from a separate source, who would have to consent to the use of their cells in another patient's body. A potential disadvantage is to the patient himself or herself, in that the cells have to be harvested in a separate procedure and expanded in culture, and there is thus an additional cost to the procedure and potential complications (e.g. infection) at the site of the other surgery.

(ii) There are currently only two types of tissue-engineered products that are FDA/EU approved and commercially available. The first is only peripherally a tissue-engineered product, as it is solely an autologous cell transplant from healthy cartilage within the joint to a defect (Genzyme Carticel). Thus, there is no scaffold. The second is a monolayer or bilayer skin-like material (Apligraf or Dermagraft), where the cell source is fetal foreskin fibroblasts from donor tissue. These skin implants are thus the only true tissue engineered products on the market.

Tissue engineering has not yet lived up to its promise due to some challenges that have arisen along the way. It has proven difficult to generate a mechanically robust tissue. There have been challenges with assembly of the devices, as they are complicated combinations of cells, scaffolds, growth factors, and often must be cultured for some time in bioreactors "in vitro" in the lab environment. The devices may need to be stored prior to use, and this is challenging with living cells. The devices have to be sterilised for implantation and transported to the clinic for attaching the device "in vivo" in the clinic by a doctor. Finally, there are challenges associated with the devices' novelty in terms of monitoring the long-term health of the tissue/implant and the patient.

(iii) Because tissue-engineered products contain living cells, the existing medical device regulations — designed for non-living implants and devices — have been found to be insufficient for regulating these products. There are thus new rules in both the US and EU. In the US the regulations were introduced in 1997, two years after the first approved biologically-active products in 1995. In the EU the new rules only came into effect in 2008, so they have not been tested or used very much yet!

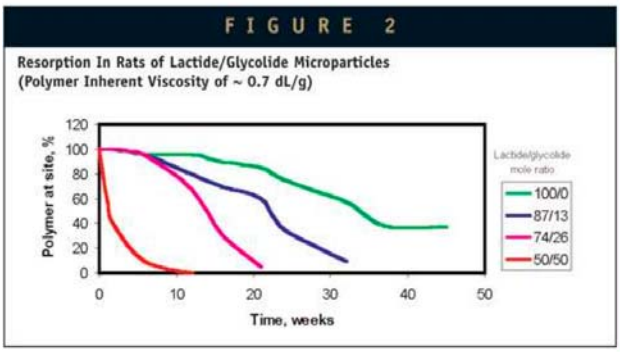
(b) (i) PLA and PGA are both esters with relatively short degradation time constants for hydrolysis and thus degradation in the physiological environment. Rough time constants are:
Poly (ortho esters) e.g. PGA: 4 hours; Poly (esters) e.g. PLA: 3.3 years
The most important factor affecting chemical stability of polymers in the body is the chemical nature of the hydrolytically susceptible groups in the polymer backbone.

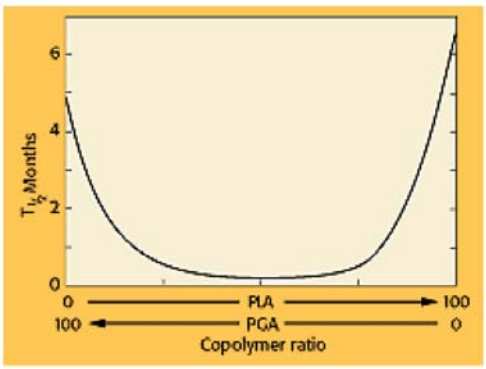
Additional critical factors are: the hydrophobic/hydrophilic character of repeat units, crystallinity, glassy vs. rubbery state (faster reactions in rubbery state), geometry (size and surface area to volume ratio) of the device. These are all important because of the relative ease of water reaching the hydrolytically susceptible groups in the backbone. Water motion through the material is by diffusion and it is slowed by hydrophobic units, by high crystallinity/low porosity and by large diffusion distances in the case of large parts with small surface/volume ratios.

Factors that cause differences in bioerosion rates for PGA [poly(glycolic acid)], PLA [poly(lactic acid)] and PGA-PLA co-polymers specifically are as follows:

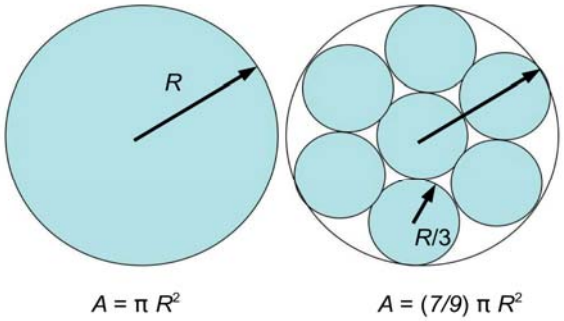
PGA and PLA have the same backbone chemistry (ester), but devices made of PGA erode faster than those made of PLA since PLA side chains are more hydrophobic. PLA-PGA blends in the 50:50 composition range are amorphous, while the pure polymers are semi-crystalline. The bioerosion rates for PLA-PGA blends depend on the crystallinity, polymer molecular weight and specimen porosity. Also affecting the degradation rates are the outward diffusion of hydrolysis by-products; if trapped, they can create pH gradients that accelerate hydrolysis in the center of the sample, leading to gradients in the specimen. Overall, there are a number of factors affecting blends and it is difficult to predict the bioerosion rate, whereas for pure materials a guess can typically be made on their rate ranking based on the polymer backbone, crystallinity, and other factors noted above. Some additional details are in this next image.

PGA	*PLA*	*Morphology*
0-25 mol%	75-100%	Crystalline
25-65%	35-75%	Amorphous
65-100%	0-35%	Crystalline





(ii) Factors to be considered include mechanical properties (bending stiffness, tensile strength). Multi-filament sutures maintain much (typically 70%) of the longitudinal tensile strength of monofilaments while exhibiting a significantly diminished (about 10%) bending stiffness due to the decreased moment of area for the smaller fibrils: bending stiffness is S = EI. For the monofilament $I=\pi R^4/4$, whilst for the multifilament $I=7\pi(R/3)^4/4$, so the multifilament is much more flexible.



For the same tensile load applied by the physician, the stress in the multifilament is only 28% larger.

Multifilaments exhibit higher friction: they tend to cause more damage when being pulled through tissue, but on the other hand the knots tend to be more stable. Monofilaments are less prone to bacterial contamination. Multifilaments erode faster than monofilaments made from the same material.
However, there is a wide range of suture types available, with different degradation times, so this parameter can be determined independently. Ultimately, the choice of suture for a particular application comes down to doctor choice.

Examiner's comments:
Well-answered question, though most candidates failed to read (a, iii) carefully and trotted out a full explanation of the approval processes in the USA and EU for medical devices, rather than identifying the specific challenges for tissue-engineered implants, as in the question.

Section C

This question is designed to test students' knowledge and understanding of the activities they have observed during their factory visits. The first part of the question requires a response identifying major themes of a factory review process and draws heavily on the structure of visits as set out in the briefing which students receive before each event.

The second part of the question requires student to demonstrate their understanding of these themes using examples of practices from the visits they have undertaken.

The marks are divided equally between the two parts of the question.

Good answers are likely to involve the following:

Part 1

- Industry level context – history, markets, scale, competition
- Company level context – scale, structure, market, products, strategy
- Material, production processes and technology
- Operations management – organisation and control
- Industrial engineering and quality
- Design management
- Human resources
- Corporate social responsibility, Health and Safety, environment and sustainability

Good answers will make reference to many of these dimensions. Excellent answers will explain their significance to the overall operation of a plant.

Part 2

Students are expected to draw upon their MET visit experience to provide illustrations of good practices in the areas of their assessment document prepared for Part 1 of this question. Good answers will provide a clear example of the assessment dimension. Excellent answers will explain the particular qualities and characteristics of the example given and why it represents good practice.