School of Mechanical Engineering	UNIVERSITY OF LEEDS

MECH3890 Individual Engineering Project

Scoping and Planning Document

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Programme of Study: Aeronautical and Aerospace Engineering
Provisional Title of Project: Heathcare Mechatronics Lab
Name of External Company (if any)**:**
Supervisor Name: Peter Culmer
Type of Project: design

***NOTES TO STUDENT**:*

a) *The font used should be no smaller than Arial 11pt or equivalent, with 1.5 line spacing and margins no smaller than 25 mm (top, bottom, left, and right).*
b) *Ensure you have discussed the content with your supervisor well in advance of the deadline for submission.*
c) *An **electronic version** of this report in pdf format must be submitted via Minerva*

Signature of Student: H. Fotheringham (signature)	**Date: 04/12/23**

Contents

1 Project Scope

1.1 Background

For some time now environmentalists have been warning that over-consumption of materials, especially fossil fuels, will cause resource depletion. To avoid running out completely and protect future generations there must be some control over the demand for these resources[1]. At the moment there is a very linear approach to the economy and product lifestyles; the product lifestyle tends to be: 'take-make-use-destroy' [2]. Recognising the limitations of this linear approach is where the concept of the *Circular Economy* becomes critical. This is the idea that a product should remain in its highest value state for as long as possible. Its highest value state is the state in which the product is functional. In the CE model recycling is one of the less favourable things to do as the product is no longer in its high-value state. Thiel found in their study that out of each of the variables that were considered the smallest reduction in impact was due to recycling [3]. However, this is better than incinerating the product which completely disposes of the materials, preventing further utilisation.

An example of this linear approach is in the Medical Industry, which overall contributes to 4.4% of the world's emissions[4]. Within the NHS the medical equipment used produces 10% of those annual emissions [5]. The reliance on throwaway practices underscores the urgency of transitioning to a circular approach which is imperative to leading us towards a more sustainable future. This idea of transitioning to a CE aligns perfectly with the NHS' promise of reaching net 0 carbon by 2045 [6].

One of the key contributors to the overall emissions of the NHS and the Medical industry are disposable items used in surgery, [7, 8]. Due to cross-contamination reasons, some devices like laparoscopic devices must be autoclaved at the end of life [9]. This process significantly increases the environmental impact of the disposal process compared to products that are simply placed into landfills. Hence there are some major challenges when it comes to re-designing/modifying current medical equipment. Guaranteeing safety, complying with medical standards and ensuring fundamental functionality introduces more difficulty in this process, emphasised by adding in re-usability. As this is such a large contributor to the NHS' environmental impact I will be focusing on taking the design principles of a circular economy and applying them to the re-designing of a laparoscopic device.

1.2 Project Aim

1.2.1 Aim

Develop a new and innovative design for laparoscopic surgery tools to minimise their environmental impact through the application of design principles of a circular economy.

1.2.2 Objectives

1. Conduct a literature review on the circular economy and how it relates to the design of laparoscopic devices
2. Develop a 3D CAD Model, representative of a current laparoscopic scissor from a physical model
3. Select and Validate an environmental impact method against the initial design of the laparoscopic scissors
4. Design a new 3D model by applying the design principles of the circular economy
5. Select and analyse environmental impact factors of the new laparoscopic scissor

Optional Build a prototype of the new device to provide tangible validation of the laparoscopic scissor design

1.3 Deliverables

- Scoping Document
  - Aims and Objectives
  - Literature Review
  - Tasks and Timeline
  - Risk Assessment

- Initial representative CAD Model
  - 3D scan of represented model
  - Design verification
  - Bill of materials
- Environmental Impact Methodology
  - Chosen methodology followed
  - Validation of methodology
- Redesigned CAD Model
  - Detailed design
  - Bill of materials
- Iterative Design Data
  - Environmental impact assessments of each design iteration
  - Design details of each iteration
- (Optional) Prototype of the device that shows the functionality of the device

2 Literature Review

2.1 Laparoscopic Surgery

Since the late 1980s Laparoscopic surgery has been making headway in the medical industry, replacing open surgery dramatically[10]. It has transformed how we perform minimally invasive surgery. Patients now receive a multitude of new benefits such as avoiding open wounds leading to less discomfort and pain, as well as an increased recovery time that has an overall positive effect on the patient's well-being [11]. The NHS predict that the recovery time for minor surgery could be as quick as 3 weeks [12] and it also provides advantages to the surgeons such as less contact with the body resulting in a lower risk of infection [11]. This type of surgery is most commonly used for *Gynecology, Gastroenterology and Urology* [13]. Moreover, several studies have been performed which show that laparoscopic surgery is becoming increasingly popular [10, 14], with Bingmer et al. showing a 462% increase in laparoscopic surgeries performed between 2000 and 2018.

This type of surgery is performed using Laparoscopic Tools and it is very straightforward for surgeons to justify using single-use Laparoscopic Tools over concerns for "quality" or "safety" [15]. However, using these single-use tools is having adverse effects on planetary health and there is little evidence suggesting this that justifies single-use items being safer [15]. Within the NHS alone medical instruments contribute to around 10% of annual emissions [5]. Disposable equipment has been identified as one of the key contributors to carbon emissions [7, 8]. Because of their use in the operating rooms, most items are not considered recyclable due to their infection and contamination potential [16]. This is why applying the design principles of a Circular Economy is vital here.

2.2 The Circular Economy

First, consider the current workings of the economy, predominately it follows a linear economy methodology. This is a very direct process, that has long been highly successful in generating wealth up until the 20th century when it started to display signs of weakness [17]. It involves taking materials from the ground, utilising them to manufacture a product, using this product and finally disposal of the product as waste [2]. On the other hand, a Circular Economy can be defined as a system where materials once extracted for use never become waste and nature is renewed; this may be done by restoration, re-engineering, or composting allowing them to go around the circular loop several times having been restored from obsolesce [18, 19]. One of the key ideas is to keep the product in its high-value state, in other words, preserve the materials' life by keeping them in the economic system and giving the product several iterations around the life cycle rather than just one [20]. This idea can be seen in Figure 1 which shows a diagram of a product's lifetime according to the circular economy. Moving towards a circular

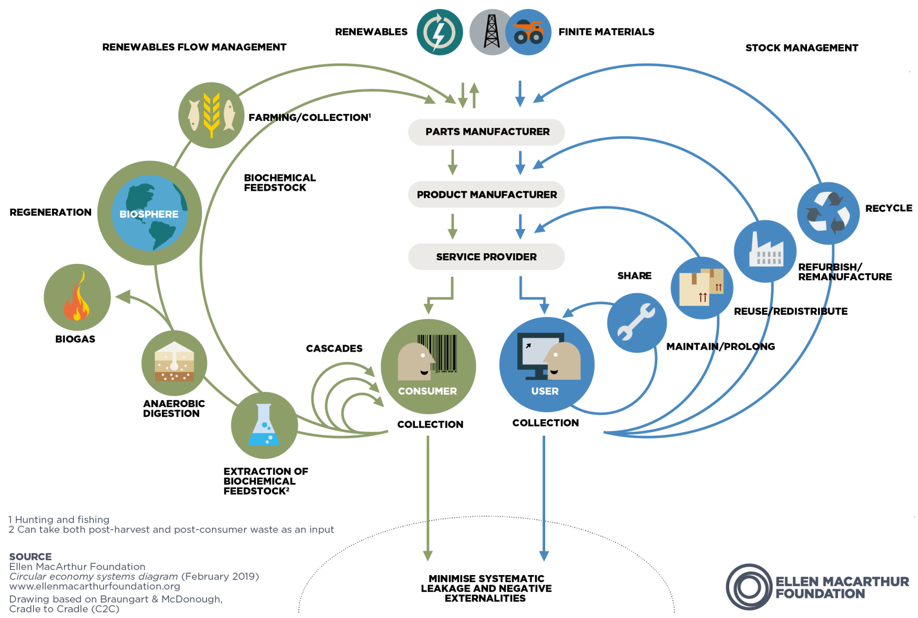

Figure 1: Butterfly diagram of the circular economy. The green represents products that are biodegradable and the blue shows more manufactured materials such as metals. The cycles represent the potential life cycles of respective products.[21]

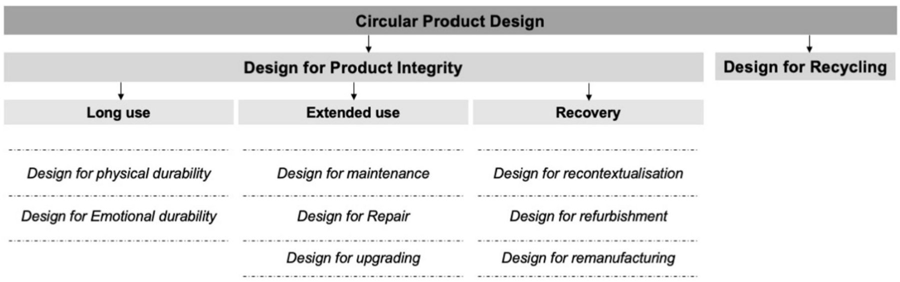

Figure 2: A view of some of the key principles that define designing for a Circular Economy [23]

economy is vital to ensure that future generations have all the resources they require to thrive as the current generations have. When it comes to designing for the circular economy there are some general design principles to keep in mind for something to be sustainable. First and foremost the design should be based on the idea of being reusable, this is one of the very core aspects of keeping the device in the economic loop. This is captured by the 'long use' section of Figure 2. Next is to allow the device to be repaired, this could entail making the device more modular so that parts can be replaced removed and repaired. There must also be a consideration of recovery, meaning once the device has become obsolete for its current use it can be transformed into a product for another use. This could mean the product is broken back down into its constituent elements for use elsewhere. Finally, at the ultimate end of a product's life it should be recyclable, for lots of materials this is not so easy hence why all of the other mentioned principles are of vital importance.

Studies have been performed that show applying all of these principles causes the environmental impact of devices designed with a circular economy in mind to decrease. For example, a study on surgical scissors demonstrated that the environmental impact can be lowered by applying some of these principles, with the removal of material having the largest effect on environmental impact [3]. Another study performed on the same device showed that by reusing and repairing the devices the environmental impact also decreased [22]. Overall this implies that applying these methods when designing will be beneficial to the environment and so should be integrated into all design processes.

2.3 Challenges Combining the Circular Economy with the Medical Industry

For the medical industry, however, applying these principles may not be so straightforward. The design of any medical product is a very high-risk field as any potential loss of functionality or slight risk increase could endanger patients' health [19]. Moreover, design for the circular economy is still in its infancy stages; there is little research on the application of a circular economy for specific fields [19], including the medical industry. Bakker also suggests that strategies or principles developed from the circular economy should be specific for each product, with the key debate in the medical industry being whether to design the device to be reusable or recyclable [24]. These all bring challenges when it comes to designing for a circular economy.

Relating this specifically to Laparoscopic devices; it is not as simple to design the devices to be reusable. One reason is because the device must be considered hygienically safe meaning undergoing disinfection and sterilisation processes [25]. Adding to this complexity is the fact that the particular sterilisation method varies depending on the device, as dictated by the *Spaulding Scale* [26, 27]. Laparoscopic Devices are considered *Critical Items*; they must experience the harshest form of sterilisation to be considered hygienically safe. Therefore, it is more complicated than just reusing the device. This is a critical point to consider when redesigning the device as it should be reusable for as long as possible but to do so it must be sterilised which could result in a loss of functionality due to the harsh sterilisation methods.

Similarly designing them to be recyclable may not be the best course of action either. Studies have shown that designing recyclable products has the smallest effect on the environmental impact [3], meaning reusing the device would have a more substantial effect on the environmental impact. For these reasons, it is clear why current devices are designed for single-use purposes and consequently why lots of the devices are not designed with the circular economy design principles in mind.

2.4 Medical Requirements

Another thing to consider is the surgeons that are going to be using these devices. The choice of instruments to be used by the surgeons is highly dependent on the surgeon's perception [28, 29, 30]. Function and precision are important to surgeons [31], some of the functions required for laparoscopic devices are listed in Table 1. It is very important to maintain these in new devices as they are the defining features and are vital for performing keyhole surgeries. As engineers, it is very easy to look past these features but for doctors and surgeons, the people using the device, these requirements make up the core foundations of the device.

Moving forward, there are several ways that we can apply these principles to their design. For example, if we remove some material from the device as discussed before, then we are wasting less material at the end of the product's life. Another idea is to make the device more modular, meaning some of the parts can be easily replaced or taken apart to be fixed. Therefore, if a blade breaks it can easily be replaced or it could be sharpened if it becomes dull. There are some cases where this type of design has been started, for example, surgical innovations have designed a new hybrid device that is partly single-use and partly reusable [42]. Rizan et al. showed through the use of a life cycle assessment that using the new devices resulted in an approximate 77% reduction in the mass of CO_2e released. This validates that following the design principles can be fundamental in ensuring that medical devices continue to be designed for long lifespans making sure they do not exit the economy as waste [23].

In contrast, Surgeons are concerned about the function of devices over time [43]. This is a valid concern as in a study on surgical scissors when reusing the devices the most common problems were blades becoming blunt or misaligned and even some screws falling out [22]. Hence, making the device more modular to replace these fatigued parts is of high importance to Surgeons and the circular economy. The current use of single-use devices may not be as safe and secure as it may first seem as they are generally produced to a poorer standard and may not go through intensive quality assurances before use [44].

2.5 Evaluating Environmental Impacts

2.5.1 Types

There are multiple methods to perform an environmental impact assessment (EIA). This is a tool that can be used to assess the impact of a project or device on the environment [45]. Within an EIA there are several different ways to measure the environmental impact of a device including Life Cycle Analysis (LCA) which is great for quantifying environmental impacts associated with a particular product.

Feature	Description	Importance
Pole Diameter	The hole size for a typical laparoscopy is between 1 to 1.5 cm [32] so the diameter of the shaft should be small enough to fit through	The size is very important as the device must be able to enter the body and still be manoeuvrable by the surgeon.
Pole Length	The devices come in many lengths. Typical values range between 250mm to 450mm [33, 34, 35, 36]	The different sizes of the pole are required for different surgeries and for different surgeon's preferences.
Medical Device Classification	Laparoscopic scissors are classed as Class IIa [37]	The device must be sterile to enter the body[25] meaning will be a large factor of the materials that are used in the device.
Sterilisation	These items are classed as critical items. [26, 27]	They must undergo the harshest form of treatment. [26, 27]
Locking Mechanism	Mechanism to lock the scissor or grasper in place	This is not present in every design but it can aid fatigue of the surgeon if they have to hold the device for a long time
Materials	Typical plastics are polyvinyl chloride (PVC), polypropylene (PP), PC (polycarbonate), and polyethylene terephthalate (PET) [38]. The different types of metals that are typically used in reusable medical devices include: Medical-grade stainless steel, titanium, and silicone [39]	These kinds of materials can be sterilised [40, 41]. Other important factors to consider are fatigue resistance, corrosion resistance, and biocompatibility.

Table 1: Critical design requirements for laparoscopic devices

Another method is a life cycle cost analysis which is great for determining all associated costs with a product's life cycle [46], however, this method lacks other key environmental impacts such as carbon output. There is also a circular economy assessment, which measures the circular economy performance of an organisation. However, it is designed for examining organisations not designs of individual products [47].

Out of those methods, the LCA is an internationally standardised methodology that is designed to quantify multiple environmental impacts associated with a product and is what was used by the majority of studies discussed in this review. These impacts include Climate Change measured in kg of CO_2 equivalent, Acidification in kg of SO_2, Eutrophication in kg of PO_2 and Energy use measured in MJ. The analysis takes into account the whole life cycle of the product starting from raw material extraction and extending to its disposal [48, 49]. It is commonly used by businesses to aid in decision making when it comes to the environmental impact of their products [50] as it is a great tool to identify opportunities for improving the environmental impact that products have at various phases of their life [51].

Referring to Figure 1 the analysis can be between different stages in the product's life cycle and there are specific terms that are used to describe each of the sections [52]. The *Cradle* is the first stage where the materials are extracted from the ground. The *Gate* is the manufacture and assembly stage. The *Grave* is the final stage, the disposal of the Product as waste. Recently there has been an increasing interest in performing *Cradle-to-Grave* analysis when it comes to products and processes [53] forming the conclusion that it is ideal to perform LCAs in this way as this covers the entirety of a product's life [48]. However, to align with the principles of a circular economy that have been outlined before, products should be designed for longevity and as such an ideal circular economy would have every product in the *Cradle-to-Cradle* life cycle. Yet, the medical industry poses some challenges when trying to introduce these principles, as has been previously detailed, where devices have to reach certain regulations to be used and once used provide a large risk of cross-contamination.

LCAs also have limitations. One such limitation is when it comes to what happens over the entire lifetime of a device, it can be very difficult to track all of the emissions from one single device. For example, when considering what happens after the device is used, it should go to be sterilised. However, some may not, some may be transported in an electric vehicle or some might be transported in bulk. Overall, the device will go through many processes that accumulate a high degree of uncertainty, presenting a significant problem when trying to generate accurate results. All these processes should be optimised [22] as they can have a large impact on the environmental impact.

2.5.2 Software and Methods

When it comes to conducting a life cycle analysis there are a variety of software packages and methods that can be used. The details of each software are shown in Table 2. There are several other features not listed, like the ability to choose the fuel a vehicle will use to travel or the ability to select how the material is extracted from the earth [66]. However, this is where SOLIDWORKS reaches its limitations as it does not have the capability of all these detailed features. To list a few of the methods that can be used, CML[70], TRAVI[71], ReCiPe[72], Eco-Indicator[73], and IMPACT[74]. Each software also has limitations on which methods they can use as shown in Table 2. Research conducted into the most commonly used LCA methodologies shows that the two most commonly used methods are CML and ReCiPe [75, 76, 77]. This is logical since the CML method is free to download and covers a variety of baseline and non-baseline factors such as Photochemical Ozone Creation Potential and Human Toxicity [70]. Similarly, ReCiPe focuses on several midpoint impact categories such as global warming and water use that through damage pathways predict endpoint factors such as damage to ecosystems or human health [72].

2.6 Conclusion

In conclusion, laparoscopic surgery is becoming more and more popular [10, 14] and the devices used for it accumulate a high percentage of the waste, within the NHS 10% of annual waste is accredited to these devices [5]. Furthermore, the combination of environmental impact testing and circular economy design principles is a reliable way to redesign any device to be more sustainable and less significant to the ever-depleting resources available. There have been studies that show the positive effect that applying these principles is having. Rizan et al. [22] showed that reusing surgical scissors has a much lower environmental impact than single-use devices. From this research, I discovered that using a LCA allows for an accurate analysis of the environmental impact of a product over its entire life cycle [48, 49]. They also provide a clear and accurate way of finding areas of improvement for the future. Limiting the analysis to carbon output will align with the goals of the NHS to reach net 0 carbon and it will be less challenging to measure compared to each of the environmental impacts. Using a *Crate-to-Gate* analysis, especially for a device of this sort will have a more definitive result as after reaching the gate many more stakeholders become involved in the life of this object making the entire life cycle very challenging to accurately map out. Furthermore, it has been shown that for single-use items, the Production stage of the device (specifically devices for laparoscopic cholecystectomy) has the highest carbon output [78]. There are a variety of different software that can be used to perform this analysis but most require a final model before the analysis can be completed. Whereas SOLIDWORKS allows real-time design changes and LCA updates [57]. I did not discover any studies that use the SOLIDWORKS Sustainability Add-in for this method so some form of validity check may be required here. SOLIDWORKS is also limited to the use of two methods detailed in Table 2 but the CML method is popular [75, 76, 77]. Thus, reasserting the fact that using SOLIDWORKS should result in a precise estimate of the environmental impacts. Finally, referring back to a study performed by Rizan et al. [42]. They concluded that the adoption of hybrid devices over single-use devices could play an influential part in satisfying carbon reduction targets. This further validates the idea that bringing the principles of a circular economy to design is paramount to reaching these targets.

3 Project Work Plan

3.1 Tasks

3.1.1 Literature review

To complete this the first stage is to outline the areas of the key areas of the project and conduct searches on relevant literature databases of these key terms. The findings of these searches will then be written up in a review.

	Features							
Software Package	Real-time design changes and analysis	Methods	Allows Material Specification	Disposal Methods	Material Transportation Consideration	Normalises Results	Output Categories	Designed for
SimaPro	No	Multiple[54]	Yes [55]	Yes [55]	Extensive [55]	Yes [54]	Extensive [54]	Academics and experienced LCA Consultants[56]
SOLIDWORKS Sustainability	Yes [57]	CML or TRACI(Tool for the Reduction and Assessment of Chemical and Other Environmental Impacts) [58]	Yes [58]	Yes but limited to 3 types[58]	Limited to country to country. [58]	—-	Limited (Carbon, Water Eutrophication, Air Acidification and Energy Consumption [58]	—-
Oneclicklca	No	Multiple [59]	Yes [60]	Yes [61]	Yes [61]	—	Extensive [62]	Construction sector [56, 63]
Ecochain Mobius	No	Multiple [64]	Yes [65]	Yes [65]	Yes [65]	—-	Extensive [64]	Product Designers[56]
GaBi (sphera)	No	Multiple [66]	Yes [66]	Yes [66]	Yes [66]	Yes [66]	Extensive [66]	LCA Experts[56]
openLCA	No	Multiple with the ability to import more [67]	Yes [68]	Yes [69]	Yes [68]	Yes [67]	Multiple [68]	Open source software available for all users

Table 2: Comparison between the important features of each of the software packages

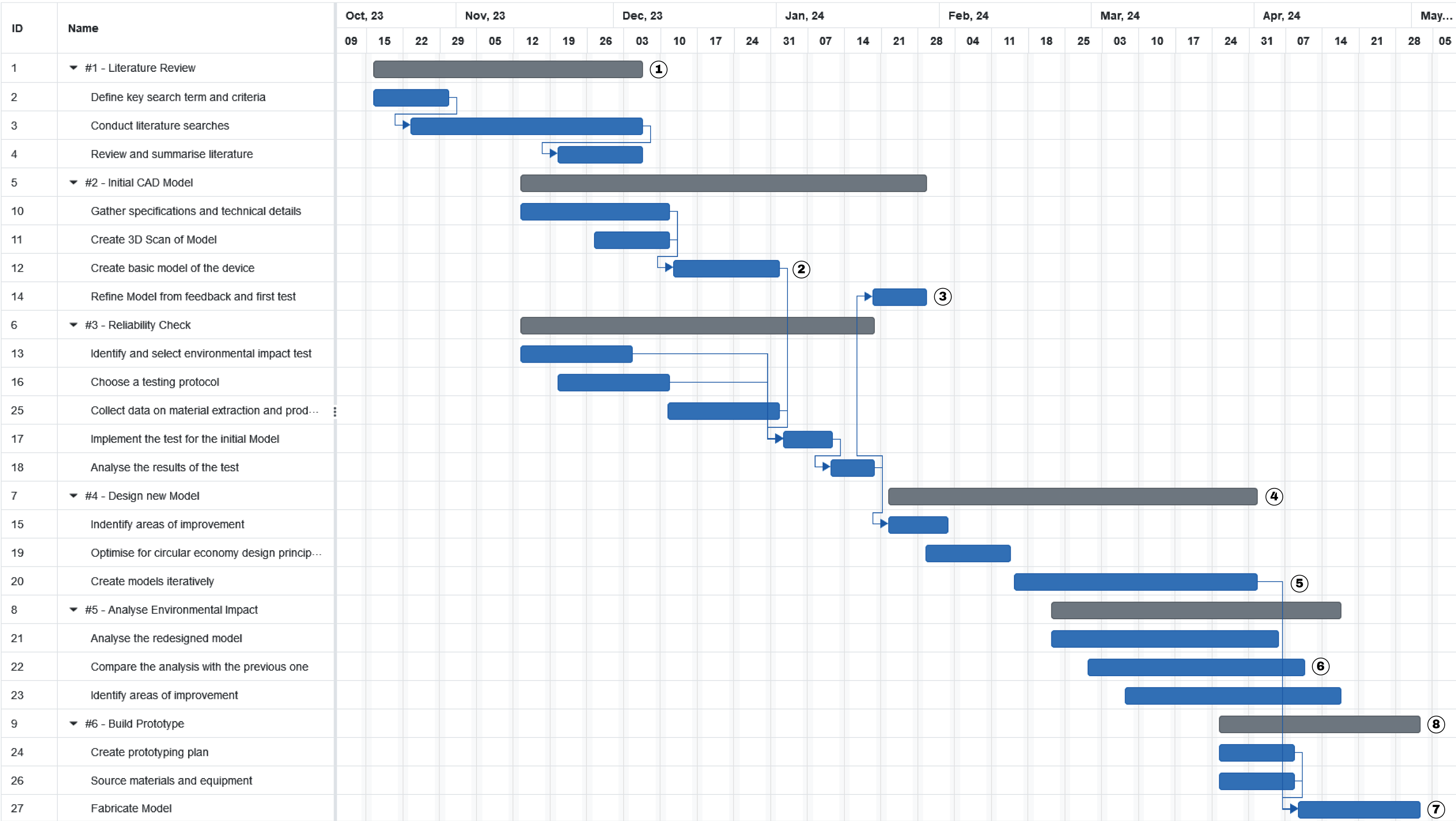

Figure 3: Gantt Chart showing each of the Objectives and the sub-tasks in order to complete the Objectives. Milestones are indicated with circles and their numbers.

3.1.2 Initial CAD Model

To form the initial representative CAD model I will use a 3D scan and physical measurements of the laparoscopic scissor to create the initial design. The final sub-task is to refine the model this will be completed after finishing the first analysis so that I can see any errors or make any improvements to make my model more accurate.

3.1.3 Reliability Check

To complete this objective, I will use the LCA method on SOLIDWORKS to determine the environmental impact of the first model. Then to validate this I will use data from a previous LCA on the same device I am redesigning [42]. This paper details the materials and their masses used inside the product and performs an LCA on a few laparoscopic devices.

3.1.4 Design new Model

Once the initial model is complete I will use the analysis to highlight the areas for improvement. Then make changes to the model and document these changes. Then I will move to analyse the new model and with the results from that analysis alter the model again. This process with continue through a few cycles.

3.1.5 Analyse Environmental Impact

First I will analyse the new model created to find its environmental impact, then use this data to create the next design. When I can compare multiple devices I can see the effect my changes have made. This will also enlighten any areas that I can improve in later iterations.

3.1.6 (Optional) Build Prototype of Model

The final task is to create a prototype of the model, which will require a plan of the methods to create the model. It then requires the facilities to be available to complete the plan and finally ending in the creation of a model.

3.2 Milestones

1. Complete Literature Review
2. 3D CAD model of device
3. Test reliability of device
4. Iterative design documentation
5. Complete the final design of the model
6. Complete the final environmental impact test of the final model
7. Final build and test or prototype
8. Project completion and documentation

3.3 Risk assessment

Table 3 presents a comprehensive table listing potential project risks, including their potential consequences. By systematically addressing these risks and developing mitigation methods, the aim is to proactively manage uncertainties, ensuring the successful and timely completion of the project.

3.4 Ethical Considerations

For my project, I will not need ethical approval. This is because to collect data for my project I do not require any human participation or any data to be collected from them. My project also focuses on redesigning a laparoscopic device to reduce the environmental impact so it is unlikely to harm the environment. All of the discussed considerations have been drawn from the flow chart from the scoping document template [79] The ethics approval form has been submitted and added to Appendix 1.

Risk	Impact	Likelihood	Severity	Mitigation	Re-assessed risk rating
Time Management	Project delays and missed milestones	Low	Moderate	Have a detailed yet adaptable project plan that includes contingency	Low
Lack of Product Access or Product Data for Design	Delays in the initial design process and hinders further progression	Low	High	Explore alternative devices and design methods. Use devices that we have access to	Low
Limited Historical Validation data	Challenging to creating a suitable benchmark, less verification of methodology	Moderate	High	Compare accurately to previous data, collaborate with my supervisor or other experts for validation, and check that general trends are followed as expected	Moderate
Scope Creep on Project Requirements	Increased workload and potential delays	Moderate	Moderate	Have a clearly defined project scope	Low
Insufficient 3D Printing Equipment	Delays in prototyping, potential limitations of design from the printers available	Low	High	Explore external 3D printing services, consider other prototyping methods	Low
Limited Software Access/ Proficiency	A long design process with potential errors	Low	Moderate	Seek training and advice on software and be adaptable to use other software if required	Low

Low Moderate High

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Increased Risk

Table 3: The scale shows Low which indicates a minimal threat that is unlikely to majorly disrupt the project, Moderate which suggests risks that are noticeable but manageable if they occur and High presents a significant impediment to the project's progress. The risk assessment table displays all of the potential risks that could occur in the Project. It shows the likelihood of them happening, the impact that this could have, an overall rating, and the response that I would take if the risk came to pass.

A Appendix A: Ethical Review Form

MECH3890 ethical approval form

Don't forget to save your answers in the next screen (you can ask for it to be emailed to you) - you need to include the file as appendix of your scoping and planning document. Once completed, if more information is required, you will be contacted by the module leader

1. What is your username? (first part of your student email, without @leeds.ac.uk) *

Harry Fotheringham

2. Does your project involve human participants or their data (e.g. interviews, questionnaires, focus group, measurement)? *

- ○ yes
- ◉ no

3. Could the work conducted during your project involve significant environmental impact?

- ○ Yes
- ◉ No

4. Unless it is a funder requirement or a legal requirement, ethical review is not needed (no need to enter an answer)

Enter your answer

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