Valid Models Only LLC.
BME 350: Introduction to BME Design
1620 BBBB

Design Inputs Draft (40 points)- Due 1/28/26 at 11:59PM

Management has given the detailed information you provided regarding the User Needs and Needs Statement to our senior level engineering teams. Our teams have enumerated several User Needs and have created a list of short-term critical design requirements.

In the accompanying document, you will see our senior-level engineers' preliminary progress on the Design Inputs section for your project report. This section includes a table for short-term, critical design requirements.

We ask you to write a first draft of the Design Inputs, which includes a written narrative justifying each design requirement and target specification. Additionally, you should summarize this section with a completed Design Requirements table.

You may wish to start by completing the table of **short-term critical design requirements, filling in any highlighted blanks left behind by the senior level engineers** *and then* write out **full descriptions and justifications (approximately 100-300 words, depending on complexity)** for each short-term critical design requirement and specification. Finally, return to your table to ensure it **concisely** summarizes your design inputs draft. For guidance, we have added highlights to indicate text that should be replaced with your own work and have added **"VMO Notes" and "Hints" that should be deleted prior to submission.**

There is no formal rubric for this assignment. Your work will be evaluated on the quality of justifications and accuracy of specification you provide. We will check that your provided target specifications accurately reflect your references and are within reasonable ranges for the project scope. Note that there is largely not a single "right answer" in this section due to the ever-evolving landscape of standards, research, and benchmarking; in fact, it is possible that documents published this very day will lend more clarity to the questions at hand than any before them. Thus, we will look here for a thorough effort to quantify and justify each of the design requirements.

Note that your assignment does NOT include long-term critical design requirements or non-critical (short- or long-term) design requirements. These would typically be included as sections within the Design Inputs. However, consider these as "above your paygrade" for the time being, as our upper-level engineers have scoped these requirements specifically for you due to their suitability to the simulation space. If you find a requirement or standard that would require a physical prototype or take time longer than what you can simulate, justify that it should be a long-term design requirement/specification that does not at this point require reporting.

Please contact us if you have any questions or concerns.

II. Design Inputs - Design Requirements and Target Specifications

VMO NOTE: This section provides a partial list of the short-term critical design requirements and specifications identified by senior engineering for our drug eluting bypass graft. For the testability of our device, each requirement must include an expanded (yet concise) rationale for the requirement, a specific target specification, and a justification for that value/restriction based on relevant literature, standards, or other credible sources. Yellow highlight designates the areas in which we would like you to focus your efforts. Please update and remove highlighting and purple text before submission. You are encouraged to edit ALL pieces and places of this document to create a cohesive narrative, though we suggest leaving the base formatting (headings, tiers, etc.) intact. Consult the examples of design requirements provided to you in your briefing (lecture) for more detail.

2.1 Short-Term Design Requirements

Short-term design requirements were identified based on literature reviews and consensus standards. These requirements represent either constraints on design decisions or performance criteria which will be tested with Solidworks and COMSOL models of the prototype, developed over the course of a semester (approximately three months).

2.1.1 Critical Requirements

The critical short-term design requirements, specifications, and justifications for our device are summarized in **Table 2.1.1. on page ___.** Written descriptions and justifications follow below until page ___.

VMO NOTE: Expand on the listed design input(s) and justification(s) in narrative form, by summarizing the relevant information from a reputable source. A few templates have been provided for you to get a feel for the style and structure. Update the above intro (e.g. what page is the table on, how long the narrative explanations stretch) to reflect your final formatting. You may need to split your table into multiple in order to not break your tables over multiple pages. Whatever you decide to do, make sure the reader can understand what is happening. Delete this note when complete.

2.1.1a In range of surrounding physiological stiffness
…

2.1.1b In range of surrounding physiological tensile strength
Expand upon this information: The circumferential tensile strength of the graft is ___. A circumferential tensile strength of ___ corresponds to data in the literature for the ___ artery.

2.1.1c Lumen does not buckle or collapse during use
Expand upon this information: Anthropometric data for the ___ artery indicates a luminal diameter of ___. Arterial thickness has been found to be ___.

2.1.1d Graft can be surgically applied to the target artery
Expand upon this information: Graft should have external diameter of ___ to be implanted in ____ artery.

2.1.1e Graft is long enough to bypass the intended stenosis

…

2.1.1f Pressure drop across stenosis indicates successful intervention

…

2.1.1g Anti-restenosis agent is present in safe concentrations

…

VMO NOTE - We expect you to pick your specifications based on your top choice of therapeutic. Use this choice for both 2.1.1g AND 2.1.1h. It is possible that values will be unavailable via literature review alone and would require further experimentation. If this is the case, document the search procedures and lack of acceptable results and check with your project manager for additional guidance. If you find that you need to switch later in the semester, this section can be updated in the final report

2.1.1h Anti-restenosis agent is present in effective concentrations

…

VMO NOTE - similar to 2.1.1g, we ask you to provide effective dosing for your top therapeutic agent choice. If you find that you need to switch later in the semester, this section can be updated in the final report.

2.1.1i Option that does not include autografts or other cell/tissue collections

While autogenous grafts are indicated as favorable in many circumstances, management has constrained this solution space to prosthetic grafts due to their superior tunability and their decreased risk of infection or surgical complication as they do not require a separate surgical site [1]. Additionally, VMO does not have the facilities or staff to support tissue engineered constructs, which would incur high costs to develop and maintain. While the exact cost would be difficult to estimate without vascular tissue engineering expertise, there is a study related to corneal endothelial tissue engineered constructs that estimates the investment cost for basic equipment to be about $50,000, and an annual recurring cost of $630,000 for laboratory rentals, quality assurance testing, consumables, packaging, and staff [2]. We suspect this cost would be similar for facilities capable of producing tissue engineered blood vessels.

VMO Note: incorporate these citations into your references, both in-text and bibliography, in your style of choice (IEEE and APA are good options, if you are uncertain what style to use).
[1] D'ayala, M., & Eidt, J. (DATE [once you read it]). Lower extremity surgical bypass techniques.
UpToDate. https://www.uptodate.com/contents/lower-extremity-surgical-bypass-techniques
[2]Tan TE, Peh GS, George BL, Cajucom-Uy HY, Dong D, Finkelstein EA, Mehta JS. A cost-minimization analysis of tissue-engineered constructs for corneal endothelial transplantation. PLoS One. 2014 Jun 20;9(6):e100563. doi: 10.1371/journal.pone.0100563. PMID: 24949869; PMCID: PMC4065108.

2.1.1j Corrosion, degradation, leaching, and reactivity of implant in physiological conditions

Update the following to reflect your project: Materials used must be known to pass appropriate ISO and ASTM standards for corrosion, degradation products, leaching, and other forms of reactivity with

physiological environments when implanted long-term. VMO NOTE – Not all categories may be relevant to your project; you only need to show standards for the categories that are relevant. If you think you may struggle to match exact geometries and materials, you may be able to justify that this requirement should be revisited after a physical prototype can be tested *in vitro* or *in vivo*. **In other words, you may be able to write a justification that this is actually a long-term critical requirement instead of a short-term critical.**

VMO NOTE 2: Keep in mind for future sections Design Outputs and V&V, **the eventual goal is to show that your chosen materials have a history of use in this application and have (cited) material standards indicating their examination in the above categories. A little research now will simplify future searches for standards.**

2.1.1k Does not cause a local immune response, fibrosis, necrosis, or other adverse effect to the surrounding tissue

Materials used must be known to pass appropriate and specific ISO and ASTM standards for the size, geometry and length of implantation time, taking the following macroscopic and microscopic observations into consideration as appropriate: fibrosis, local tissue degeneration, inflammatory cell infiltration, necrosis, cellular integration, and material fragmentation and debris (ISO 10993-6). These design specifications will be updated once the materials, size, and geometries are decided. Future testing may include: (HINT: check the standards passed by some of the existing products you found during the user needs, and list standards related to the host responses mentioned above).

VMO NOTE: The narrative for this design requirement will most likely be TBD until further design work is completed - hence why it is mostly unhighlighted. **We recommend using the standards that existing products were tested with for this section of the Design Inputs draft.** Use what you've learned to justify that this DR should be shifted to long-term critical.

Table 2.1.1. Critical short-term design requirements, inputs, and justifications.

Index	Need Category	Requirements	Target Specifications	Justifications
2.1.1a	Durability / Safety	In range of surrounding physiological stiffness	..	(Hint: Literature Review – arterial stiffness)
2.1.1b	Durability / Safety	In range of surrounding physiological tensile strength	..	(Hint: Literature Review – arterial tensile strength)
2.1.1c	Feasibility	Lumen does not buckle or collapse during use	..	(Hint: what geometries matter? What does collapse mean here?)
2.1.1d	Feasibility	Graft can be surgically applied to the target artery	External diameter: (this might be a range)	(Hint: which arteries are most often affected by PAD? Should the bypass be the same size or a different size?)
2.1.1e	Function	Graft is long enough to bypass the intended stenosis	Bypass length: (this might be a range) Insertion angle: (this might be a range)	(Hint: different severities of PAD have different lengths – which one are you focusing on? With the insertion angle, how long does the bypass need to be?)
2.1.1f	Effectiveness	Pressure drop across stenosis indicates successful intervention	..	(Hint: research/consider metric(s) useful to clinicians or researchers in assessing hemodynamics before and after intervention)
2.1.1g	Safety	Anti-restenosis agent is present in safe concentrations	Local concentration of the therapeutic in the blood/arterial tissue does not exceed identified toxic concentration at any time in ____ days.	(Hint: Lit Review with toxic thresholds; *in vitro* data may also be helpful here, as may more systemic parameters such as MTD. Also see note below on possibility for "further experimentation")
2.1.1h	Effectiveness	Anti-restenosis agent is present in effective concentrations	Local concentration of the therapeutic in the blood/arterial tissue remains above identified minimum concentration at all times in ____ days.	(Hint: investigate parameters such as EC50; note that for this section and the above, it is possible that values will be unavailable via literature review alone and will require further experimentation. If this is the case, document the search procedures and lack of acceptable results)
2.1.1i	Feasibility	Option that does not include autografts or other cell/tissue collections	Material used in device is a synthetic or natural biomaterial	Management will reject autogenous grafts due to risk, time, and practical constraints[1]. Management will also reject tissue engineered constructs due to cost and personnel constraints [2]
2.1.1j	Biocompatibility	Corrosion, degradation products, leaching, and other forms of reactivity of long-term implants in physiological environments are within standard limits.	VMO NOTE: Normally, you would list the specific measurements from the ISO/ASTM/etc tests here, but you may find you can justify "Shifted to Long-Term Critical"	VMO NOTE: Normally you would summarize specific ISO/ASTM/etc tests here as well, but you may find you can justify "Shifted to Long-Term Critical"
2.1.1k	Biocompatibility	Does not cause a local immune response, fibrosis, necrosis, or other adverse effect to the surrounding tissue	VMO NOTE: Normally, you would list the specific measurements from the consensus standards here, but you may find you can elaborate on plans to match existing geometries and materials and so justify "Shifted to Long-Term Critical".	VMO NOTE: Normally you would summarize consensus standards for existing devices you found in User Needs. You may find you can justify "Shifted to Long-Term Critical"