Bioengineering Day Poster Addendum — 02BTECReimold

1. **Desired Needs**
    - One major need was to create a testing system that could quantify device function, which was fulfilled through the use of fluid dynamics principles and integration of various sensor types.
    - Another need was to ideate and implement design changes to the AUS cuff, which was carried out through CAD modeling and the development of a FEA platform to perform preliminary pressure/tension analysis on device iterations
2. **Constraints**

    a) Safety/Regulatory Affairs: Could not verify biomaterial changes due to testing constraints, and therefore had to approximate with similar materials

    b) Risks: Changes could potentially introduce new failure modes

    c) Global Impact: Surgery to implant device is specialized

    d) Manufacturability: Device would require complex manufacturing process and is therefore difficult to prototype

    e) Quality Control/Marketability: Very marketable but is difficult to quality control on a small scale due to how fine-tuned the device is
3. **Engineering Standards**

    Major engineering standards relevant to this project include ISO 10993 for biocompatibility of medical devices, ISO 14971 for medical device risk management, and ISO 14630 for requirements of non-active surgical implants.
4. **Ethical, Environmental, or Societal concerns**

    This project raises ethical and societal concerns related to patient safety, accessibility, and long-term quality of life, as modifications to an implantable medical device must not introduce additional risks such as tissue damage, infection, or device failure.
5. **Active Teamwork & Leadership**

    Since this was the first time this project has been implemented at UCSD, we had to go through a lot of decision making for the direction of the project, which involved a lot of constructive discussion and splitting work so that multiple avenues could be explored to meet our goals and deadlines.
6. **New knowledge, Initiative, & Persistence**

    This project was particularly conducive to being creative because of its' open-ended nature, so we were very motivated to try different ways of accomplishing our goals, leading failures which then informed our successes!
7. **Innovative and/or entrepreneurial ideas**

    Our benchtop model could help reduce R&D costs for the rapid prototyping phase of devices designed to address urinary incontinence, even beyond the AUS; furthermore, our work to characterize and improve upon the AUS itself has the potential to improve QOL for a significant patient population.