

Perfusion decellularization-recellularization bioreactor for laryngeal tissue engineering

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Problem Statement

The purpose of this project is to design a sterile bioreactor for whole organ tissue engineering of the human larynx, as well as comparable large animal models such as the pig or dog larynx. The bioreactor must be capable of performing two different processes: perfusion-decellularization of the larynx to create an acellular scaffold, and perfusion-recellularization of the acellular scaffold using vocal fold fibroblasts and other cell sources.

Client Requirements:

- The bioreactor must be sterile and have parts that can be replaced or autoclavable
- The bioreactor must easily be able to fit inside of the incubator
- The bioreactor should be capable of decellularizing and recellularizing the larynx
- The bioreactor must be able to function for days at a time

Design Requirements:

1. Physical and Operational Characteristics

- Performance Requirements:* The bioreactor needs to be capable of decellularizing a larynx to produce an acellular scaffold and subsequently provide an environment to recellularize the scaffold. This will be accomplished through perfusion pumps through the vasculature and trachea.
- Safety:* The device needs to be sterile if the larynx will be used in future transplantation. Additionally, the device should contain sufficient safeguards against user chemical exposure.
- Accuracy and Reliability:* The flow rate through the vasculature should not exceed physiological values and be able to maintain function throughout the entire decellularization-recellularization process.
- Life in Service:* For the decellularization process, the bioreactor should perform for a minimum of two days. For the recellularization process, the bioreactor needs to be able to perform for a minimum of 3 weeks. The bioreactor must also be reusable.
- Shelf Life:* The bioreactor should be capable of performing for 5 years.

- f. *Operating Environment:* The bioreactor should be fit to operate in an incubator environment. Typical conditions include 37degrees C, 5% CO₂ and humidity. The device will also be exposed to various chemicals and liquids which are commonly found in a bioreactor environment.
- g. *Ergonomics:* The bioreactor needs to be movable and reasonable for one person to carry. It also must open to provide easy access to the tissue specimen.
- h. *Size:* The reactor itself must be able to house a human or a large animal model larynx. The dimensions of the bioreactor must not exceed 50.8 x 54.1 x 68.1 cm.
- i. *Weight:* The product must be handled easily by one person without excessive strain.
- j. *Materials:* All materials used in the bioreactor must be sterile or autoclavable. None of the materials should degrade after exposure to detergents and other chemicals used during the decellularization and recellularization processes.
- k. *Aesthetics, Appearance, and Finish:* The bioreactor must look like it fits in a laboratory setting.

2. Production Characteristics

- a. *Quantity:* 1 deliverable
- b. *Target Product Cost:* \$1-3000

3. Miscellaneous

- a. *Standards and Specifications:* N/A
- b. *Customer/Patient related concerns:* N/A
- c. *Competition:* There are companies that already make bioreactors but none that are specifically made for the larynx.