Executive Summary

If an illness or injury near the lungs occurs, it can cause the lungs to fill with fluid, leading to suffocation. The chest tube drainage system used on Earth relies on a wet seal to prevent back flow and provide an indication of air leaks. This wet seal relies on a distinct air-water interface and does not function without gravity.

Therefore, there is a need for a system that provides suction and chest tube drainage, while preventing back flow and providing an indication of air leaks, without the use of a water seal or gravity.

In order to resolve the two shortcomings of the current wet seal system under zero-gravity, our device will use a Heimlich Valve to prevent backflow of the fluid back to the patient and a pressure sensor to detect air leaks and indicate when the chamber needs to be changed.

Clinical Need

Used to remove air (pneumothorax) or fluid (pleural effusion) in the lungs without the use of gravity.

- **Incidence Rate:**
  - Primary spontaneous pneumothorax:
    - 7.4 and 1.2 cases per 100,000 person-years in males and females, respectively
    - Age adjusted incidence rate is about 200 cases per 100,000 person-years
  - Pleural effusion:
    - Estimated to be at least 1.5 million cases annually in the US
    - 320 cases per 100,000 people in the world

- **Mortality:**
  - 15% mortality rate for secondary pneumothorax
  - Malignant pleural effusion has median survival of four months and mean survival of less than one year

Market

- The only current market is through NASA, who is willing to invest in a chest tube drainage system that works in zero gravity for their astronauts in case a collapsed lung occurs during a space mission.
- Selling price estimated at $100, which would produce no profit, due to the humanitarian use device exemption
- As the space travel industry grows, potential market for the product may also grow

Novelty of Concept

- Our device uses layers of cellulose sponges and sodium polyacrylate powder to block lung fluid from entering the central vacuum system
- Traditional three-bottle chest tube drainage system uses wet seal, which is only possible using gravity, in order to:
  - Prevent backflow to patient
  - Instead, use a Heimlich valve (one-way valve)
  - Indicate a leak in the system
  - Instead, add a pressure sensor and indicate when deviation from normal pressure occurs

Description of Design/Design Specifications

The final design prototype consists of three main components: the vacuum which supplies suction for the chest tube drainage, the central tube filled with sponge material, and the tubing connecting the patient to the central tube and the central tube to the vacuum. These all create a sealed system that provides suction to remove undesired fluids from the interpleural space in the patient's lungs.

Features of Final Prototype:

- Inlet
  - Tubing from patient connects to the Drain Zero product at this location
  - Disposable Sponge Casing
  - Provides snake-like pathway for fluid flow to maximize compactness of the design
  - Contains three (3) sponges that retain liquid expelled from the chest while allowing gaseous material to pass through (maintains vacuum functionality)
  - Reusable Electronics Component
  - Contains the pressure sensor, alarms, etc. that would otherwise be expensive to replace for every use
  - Tubing within allows analysis of flow (ex. pressure) that can also be cleaned and reused
  - Easy interlocking mechanism with Disposable Sponge Casing provides reusability for electronics
  - Outlet
  - Connects system to the vacuum, which pulls the fluid through the entire product

Costs

<table>
<thead>
<tr>
<th>Part Description</th>
<th>Quantity Required</th>
<th>Unit Cost</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acrylic Tube</td>
<td>17 in</td>
<td>$3.28 per inch</td>
<td>$55.66</td>
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<tr>
<td>Acrylic Ends</td>
<td>32 in²</td>
<td>$0.07 per square inch</td>
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<td>Threaded Attachments</td>
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<td>$2.04</td>
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<tr>
<td>Hose</td>
<td>36 in</td>
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<td>Heimlich Valve</td>
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<td>Sponge</td>
<td>60 in²</td>
<td>$0.09 per cubic inch</td>
<td>$5.40</td>
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Sub Total: $69.47

<table>
<thead>
<tr>
<th>Operation</th>
<th>Time Required</th>
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<tbody>
<tr>
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<tr>
<td>Quality Control</td>
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Sub Total: $25

Total Cost: $94.47

Anticipated Regulatory Pathway

- Class II medical device
- Humanitarian Use Device Exemption
- Extremely small market: the incidence of events requiring chest tube drainage systems in zero gravity is less than 4,000 per year
- No other solutions in the market
- Device cannot be sold for a profit

Future Work

- A disposable sponge container that connects to electrical components for reusability
- Velcro on system to prevent it from flying around in space
- Hooks for wrapping tubing to prevent tripping hazard
- Multiple vacuum connectors to be used on any of the vacuum outlets in space station
- Vacuum regulator to keep the force of the vacuum independent from vacuum being used

Acknowledgments

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Footnotes and References

1 Bioengineering, University of Louisville
2 Biomedical Engineering, Carnegie Mellon University
3 Chemical Engineering, Carnegie Mellon University
4 School of Design, Carnegie Mellon University
5 Electrical and Computer Engineering, Carnegie Mellon University
6 Mechanical Engineering, Carnegie Mellon University