

Above Elbow Prosthetic (AEP): An Extension to the LN-4 for Transhumeral Amputees

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Need and Objective

Need

- Around 2.3 million people in developing countries have necessary limb amputations due to events such as:
 - Civil unrest leading to injury
 - Workplace injuries
 - Infection of wounds without proper treatment
 - Birth defects from abnormal fetal development
- Currently, patients with residual limbs that extend below the elbow can currently be fitted with the LN-4 prosthetic hand (provided by the Ellen Meadows Foundation and Rotary Clubs)
- However, for those with amputations above the elbow (transhumeral amputations) or no limb altogether, this prosthetic cannot be utilized (which is pictured in Figure 1).

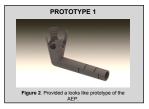


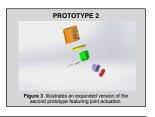
Objective

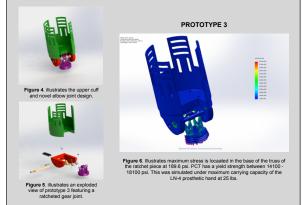
Figure 1. LN-4 prosthetic hand and assistive shoulder strap.

We aim to develop an above elbow extension for the LN-4 that matches the price, durability, and application process of the LN-4 in below elbow use.

Prototypes







Future Directions

Manufacture

- Injection molded PCT 40 percent glass/mineral filled
- Metal casting of magnesium alloy AZ19D
- Highest cost will be initial mold manufacture, which would be offset by production number (likely around ten thousand)
- Cost of each part would be around one hundred dollars

Market

- As a prosthetic aid in low resource areas, this would be funded by a humanitarian minded company or individual (such as the Ellen Meadows Foundation and rotary clubs)
- In the United States, the prosthetic would have to be modified to include a prosthetic hand
- However, this would likely still be marketable in the United States because the overall cost would be lower than many current mechanical and all mechatronic prostheses

FDA / Medicare

- AEP falls under Class I categorization for FDA
- Regulated under external prosthetic code 890.3420
- Product is 510(k) exempt since it has substantial equivalence to devices on the market currently
- Reimbursement within developing countries will be covered by the Ellen Meadows Foundation
- Within the US it is reimbursable by Medicare/Medicaid billed under L codes with justification