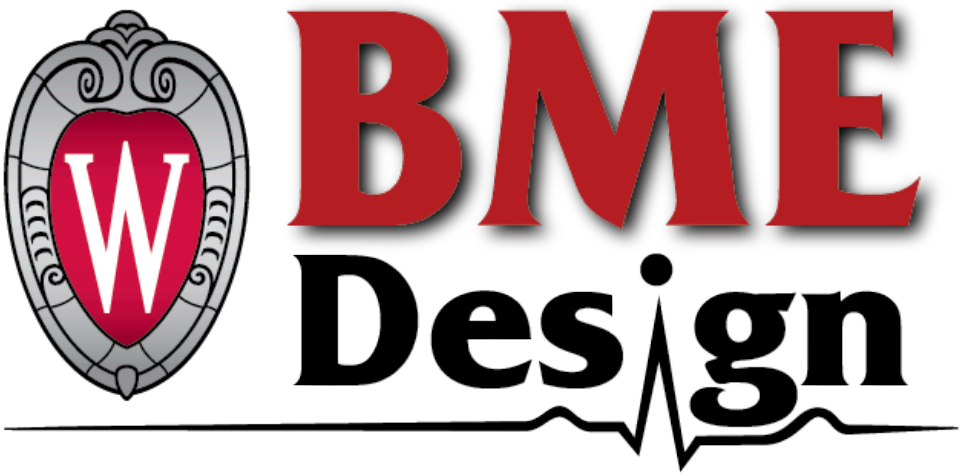

Amputee Advanced Donning Device

Product Design Specification

BME 400, Lab 306

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Function:

During physical rehabilitation, it is critical for amputee patients to wear a specialized compression garment known as a shrinker sock. A shrinker sock aims to shape the residual limb in preparation for prosthetic fitting and prevent post-operative complications like swelling and excess fluid retention. To apply the shrinker, patients currently rely on basic donning tubes, where the shrinker is stretched over a plastic tube and pulled over the residual limb. Because shrinkers are designed to apply strong, consistent compression, they can be very difficult to stretch over donning tubes. This challenge is especially significant for elderly patients, who may have limited strength, dexterity, or mobility. This device aims to create an advanced donning device that stretches the garment to the desired diameter using electronics and mechanical means, simplifying shrinker application and eliminating the need for manual user input to stretch the garment.

Client Requirements:

- The device must be able to withstand the compressive forces of a shrinker sock, effectively simplifying the application of the shrinker sock.
- The device must be durable as it will be used multiple times per day.
- The device must be able to withstand basic sterilization with a disinfectant wipe or bleach solution.
- The device should be portable and weigh no more than 5 kg.
- The production cost of the device must be less than $500.

Design Requirements:

1. **Physical and Operational Characteristics**
    a. **Performance Requirements**:
        i. The device will be used to apply shrinker socks for patients with transtibial amputations, also known as below the knee amputations, requiring the device to expand the shrinker sock to a diameter of 25.4 cm [1].
        ii. The device must be able to withstand the 30-40 N force applied to it by the shrinker sock when stretching to the required diameter [2].
        iii. The device must not require excessive strength, bending, or fine motor skills to operate to ensure accessibility for patients.
        iv. The device should be lightweight and portable to ease use outside of a clinical setting.
        v. The device should be 50 cm long to prevent any potential bottom of the device from contacting the patient [3].
    b. **Safety**:

i. All mechanical and electrical driving mechanisms must be isolated from points of contact between the device and patient. Mechanical and electrical fail-safes should be implemented to prevent over and under expansion.
ii. Any surface of the device that may come into contact with the patient should be rounded or smooth. The device should be lightweight and ergonomically designed to minimize pressure points.
iii. The materials used in contact with the skin must comply with ISO 10993-1:2018, which specifies the biological evaluation of medical devices to prevent irritation and guarantee biocompatibility [4].
iv. The electrical components must comply with IEC 60601-1, which standardizes safety and performance of medical electrical equipment [5]. All electrical components must be securely enclosed in a shock-resistant housing to prevent accidental contact and electrical injuries.

c. **Accuracy and Reliability**:
i. The target stretch diameter of 25.4 cm aligns with anthropometric data recorded by the CDC from 1999-2002. The average calf circumference for males aged 20 years and older is 39.1 cm, which translates to an average approximated diameter of 12.4 cm [6]. The stretch diameter of 25.4 cm will provide adequate space to manipulate the shrinker sock before application.
ii. The device must be able to resist the compressive forces of the shrinker sock by consistently generating the required force to stretch the shrinker.

d. **Life in Service**:
i. The device must remain functional throughout the rehabilitation period, spanning from the removal of surgical stitches to the fitting for a prosthetic limb. This rehabilitation period varies per patient, typically spanning several months [7].
ii. A patient would generally use the device about two times per day to apply a shrinker sock following activities such as bathing or skin checks. In a clinical setting, the frequency of use would vary depending on patient volume and demand.

e. **Shelf Life**:
i. The shelf life of the device will be finalized after material and component selection. Factors such as material degradation, battery stability, and long-term reliability of electronic components will need to be considered. The current design goal is to achieve a shelf life of approximately 5-10 years.

f. **Operating Environmen**t:

i. The device is intended for use in both home and clinical settings. It is not expected to be used outdoors and should be operated in temperatures ranging from 15°C to 27°C [8].

g. **Ergonomics**:
   i. The device should not have sharp edges that could cause cuts or injuries to the patient.
   ii. The force required to operate the device will be minimized to accommodate older patients and users with reduced hand strength or dexterity.

h. **Size**:
   i. The device will have a diameter of 25.4 cm when fully expanded, which is comparable to existing donning tubes and sufficient to accommodate the average male thigh circumference [1].
   ii. The device will have a length of approximately 50 cm to allow the shrinker sock to be positioned and applied properly to the patient without causing discomfort [3].

i. **Weight**:
   i. The device will weigh under 5 kg, allowing it to be portable as needed for patient use. It must be able to be moved between clinical rooms for use with multiple patients.

j. **Materials**:
   i. The material that will be used for construction of the device needs to be lightweight to be accommodating for patients with low dexterity.
   ii. All finalized device components that come into contact with the user's skin must be biocompatible and non-irritating. Additionally, these components will withstand routine cleaning and disinfection in clinical settings without deterioration or degradation of device performance, appearance, or quality.
   iii. The materials must be sufficiently durable to withstand the 30-40 N compressive forces exerted by the shrinker socks when stretched to a diameter of 25.4cm [2].

k. **Aesthetics, Appearance, and Finish**:
   i. The device will have a professional, high-quality appearance.
   ii. The design will allow for simple cleaning and disinfection using disinfectant wipes or a bleach solution.
   iii. The device will be accessible and easy to use for patients with limited dexterity.

2. **Production Characteristics**
   a. **Quantity**:

i. There will be a total of one unit constructed for this project. More prototypes and development may be made in the future, but are outside the scope of this project.

b. **Target Product Cost**:
   i. The target product cost will be within $500 for a single unit.

3. **Miscellaneous**
   a. **Standards and Specifications**:
      i. The final prototype must abide by the regulations for Class I medical devices under FDA 21 C.F.R. Part 890 [9].
      ii. The final prototype will contain electronic components and may be subject to IEC code 62353:2014, ensuring that the electronic medical device does not cause harm to the user [10].
      iii. Due to the donning device having the possibility to come into contact with the patients' body, it must also follow standard ISO 10993-1, ensuring additional safety precautions to be taken in device construction [4]. These standards set a precedent for the testing that needs to be performed after the device's production.
   b. **Customer**:
      i. The primary users of this product are below-knee amputation patients, which largely consists of individuals affected by diabetes, leading to a need for amputations due to peripheral neuropathy [11]. Certain end user groups that could benefit the most from this device are patients that are elderly, have peripheral neuropathy, and those with arthritis or joint pain.
   c. **Client-related concerns**:
      i. As this device will be used with multiple patients in a clinical setting, it will need to be sterilized between uses. This device should be able to withstand basic sanitation with a disinfectant wipe or a bleach solution.
      ii. The device must be made so it stretches the shrinker sock to a fit diameter, ensuring that overstretching and damage to the sock are avoided.
   d. **Competition**:
      i. Existing shrinker sock applicators within the clients' vision do not yet exist on the medical device market.
      ii. Patent US4541554A functions as an applicator for post surgical dressings and may be used as design inspiration, but lacks electronic components, making this design inaccessible for patients with low dexterity [12].
      iii. Similar patents have also been developed that discuss and model shrinker sock applications, but do not allow for low-dexterity use due to a physical hand crank [13]. This device will exceed these designs by allowing for electronic components to handle all mechanical work, rather than the patient or physician.

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