HeadVac: Product Design Specification

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Project Title: HeadVac

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Function

Design a negative-pressure wound therapy (NPWT) accessory ("HeadVac") that reliably forms and maintains a seal around rhytidectomy (facelift) incisions—especially bilateral pre-auricular and post-auricular regions with the ear as the primary focus—to evacuate fluid, reduce hematoma formation, and protect perfusion of facial skin flaps. The system should deliver constant negative pressure within safe limits, conform to complex facial contours and hair-bearing skin, and be simple for nurses to apply, remove, and replace in the clinic and at home.

Client requirements

Pre-auricular incisions were identified as the primary area of interest, with additional accommodation for post-auricular and temporal incision variants. The device should provide constant negative pressure therapy, with preliminary targets based on incisional NPWT standards of approximately –125 mmHg, though the acceptable operating range must be verified with the surgical team.

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements**: The performance demanded or likely to be demanded should be fully defined. Examples of items to be considered include: how often the device will be used; likely loading patterns; etc.
        i. The performance demanded of the device must be fully defined to ensure safe and effective clinical use. "Negative Pressure Wound Therapy (NPWT) dressings can be left in place for **24 to 72 hours**, depending on wound characteristics." [1] with potential use extending up to **7 days per patient episode**, reflecting current clinical practice for negative pressure wound therapy.

ii. During this time, the system must withstand both **static loading** from the headband securing mechanism and **dynamic loading** resulting from patient movement. Common disturbances include jaw movement during speech or mastication, neck rotation, or coughing, each of which may disrupt the seal or induce pressure fluctuations. [2].
iii. To meet these demands, the device must detect and correct such disturbances without compromising pressure stability or therapeutic effectiveness.
iv. The negative pressure system must maintain a consistent therapeutic range suitable for delicate craniofacial tissues. General clinical practice indicates that “a continuous pressure of −80 mmHg to −125 mmHg is most commonly used in traumatic orthopaedic wounds” [3], though ranges between −50 mmHg and −150 mmHg are documented depending on wound type and sensitivity [4]. For cranial applications, the device will be required to deliver a continuous **−125 mmHg ± 5 mmHg**to ensure both safety and efficacy.

b. **Safety**: Understand any safety aspects, safety standards, and legislation covering the product type. This includes the need for labeling, safety warnings, etc. Consider various safety aspects relating to mechanical, chemical, electrical, thermal, etc.
i. NPWT devices are classified as Class II medical devices, requiring adherence to **FDA** design controls (21 CFR 878)[5] and special controls that address risks such as infection, bleeding, and electrical hazards. Compliance with **ISO 14971** (risk management) and **IEC 60601-1** (basic safety and performance) is required for commercialization
ii. Device labeling must follow the **FDA’s *Guidance on Medical Device Patient Labeling***, including clear warnings about contraindications (e.g., untreated osteomyelitis, exposed organs, necrotic tissue). Warnings about bleeding risks, infection control, and patient monitoring requirements are mandated, and labeling should include standardized symbols from **ISO 15223-1** [6]
iii. “The patient labeling should contain information regarding the indications for use, directions for use, and possible adverse reactions written in lay terms for comprehension by the general public.” [7]
iv. All patient-contact components must be biocompatible per **ISO 10993-1**. Specific hazards include sensitizers such as latex, which require warnings on labeling per **21 CFR 801.437**. The FDA also requires evidence of sterilization validation and microbial barrier performance for disposable dressings [8]

c. **Accuracy and Reliability**: Establish limits for precision (repeatability) and accuracy (how close to the "true" value) and the range over which this is true of the device.
i. Although the FDA does not provide a specific allowed deviation from the “true” value in order for a product to be commercialized, it issues a guideline for design controls. Each manufacturer shall establish and maintain procedures to control the design of the device to ensure that specified design requirements are met during all steps of the design process [9]. Some major design considerations the team needs to consider under the pretense of precision include the negative pressure system and fluid drainage system.
ii. With regards to the negative pressure system, general clinical practices indicate “a continuous pressure of -80 mmHg to -125 mmHg is most commonly used in traumatic orthopaedic wounds” [10]. However, the normal levels can vary between -50 and -150 mmHg depending on wound type and sensitivity [11].

Currently, the FDA consensus standard is within the aforementioned range, but more focused around -125 mmHg to ensure both patient safety and product effectiveness for dense orthopedic wounds. The team's product aims to deliver a continuous pressure to the cranium, an area more delicate than normal orthopedic wounds; hence, a continuous ***-125 mmHg ± 5 mmHg*** pressure will be outputted by the pressure system to ensure patient safety and product effectiveness in the cranial area. Negative pressure validation on a flesh-like material must be performed before each use to ensure the suction pressure is within the defined range.

iii. With regard to the fluid drainage system, the team must ensure that fluid reflux is at a minimum. Fluid reflux is very dangerous and could severely harm the patient if the blood is contaminated within the drainage system, thus extensive testing and design validation must be performed. The team aims for a ***0 µL backflow of fluid, with a tolerance of 1µL.***

d. **Life in Service**: Establish service requirements, including how short, how long, and against what criteria? (i.e., hours, days of operation, distance traveled, no.of revolutions, no. of cycles, etc.)
   i. The product will be used post-Rhytidectomy. The headband and tubing will be one-time use, and will be replaced daily. The negative pressure system and fluid collection container are reusable with a 10-year lifespan. The team is not required to develop a new NPWT unit, so they intend to purchase a unit with the aforementioned lifespan. Every 6 months, maintenance and qualification will be conducted on the entire negative pressure device to ensure it is up to standard.
   ii. With regards to patient usage, the device will be used for up to an hour a day for a week post-surgery. The team aims for an optimal recovery time while also allowing the patient to continue with their daily activities.

e. **Shelf Life**:
   i. The device will need to last from the time it is shipped to the hospital until after the patient is done with its use. Plastics used for headbands do not normally degrade over time under moderate condition,s such as the conditions present in a hospital, so shelf life is not a major concern until years or decades have passed.
   ii. Patients will wear the headband for up to 7 days, beginning immediately after surgery in the operating room [12].

f. **Operating Environmen**t: Establish the conditions that the device could be exposed to during operation (or at any other time, such as storage or idle time), including temperature range, pressure range, humidity, shock loading, dirt or dust, corrosion from fluids, noise levels, insects, vibration, persons who will use or handle, any unforeseen hazards, etc.
   i. The device will be used and handled in a well-controlled operating room environment, which will be controlled for temperature, pressure, humidity, and air particulate concentration.
      1. Standard 15.01.02 of the American Society of Heating, Refrigerating, and Air-Conditioning Engineers states that temperature must be maintained for “patient comfort” and “safe equipment operation”, humidity must be between 20%-60%, and that air pressure must remain positive to

disallow “contaminants from entering sterile fields” [13]. The device must withstand these conditions.

ii. The device will only be operated by nurses, surgeons, or other medical personnel trained specifically in NPWT.

iii. The device, particularly the segments exposed to its generated negative pressure conditions, will be exposed to -125 mmHg pressure for many hours at a time, up to 7 days [14].

g. **Ergonomics**: Establish restrictions on the interaction of the product with man (animal), including heights, reach, forces, acceptable operation torques, etc.

i. There are no restrictions on the characteristics of individuals using the device (i.e., weight, gender, age, height, race, etc). The device must be comfortable and adjustable for the patients. Normally, the maximum negative pressure allowed would be 150 mmHg subatmospheric (- -150 mmHg). However, the team decided to lower its allowed maximum value to 130 mmHg (-130 mmHg) due to the device's intended use on the delicate cranial area.

h. **Size**:

i. The HeadVac device will cover facelift incisions and flap surfaces on the cheek and surrounding ear area.

1. The headband must be slim, lightweight, and non-bulky so that it fits comfortably on a patient's head post-rhytidectomy.
2. The headband must not be too tight on the skin.

ii. The Headvac device will be single-patient use NPWT (sNPWT) [15].

1. The headband will be adjustable and disposable.
2. The vacuum tubing will be disposable.

iii. Tubes must not be placed on skeletal pressure points to prevent the formation of pressure ulcers [16].

iv. Future adaptations may include extensions to accommodate scalp incisions.

i. **Weight**:

i. The Headvac device must be lightweight and non-restrictive.

ii. The Headvac is intended for use by ambulatory patients.

j. **Materials**: Establish restrictions on certain materials that should be used and if certain materials should NOT be used (for example, ferrous materials in an MRI machine).

i. The device will be secured within a headband spanning the circumference of the head.

1. The outer shell of the headband should be made of a comfortable and flexible material. Thermoplastic polyurethane is flexible, biocompatible, and often used in medical devices [17].
2. Alternatively, the device can be disposable with a more comfortable material choice for the patient. Nylon and polyester textiles are commonly used as prosthetic straps and compression garments [18].

ii. The HeadVac device will utilize negative pressure wound therapy. To secure the incision sites, dressings used in post-operative care and negative pressure wound therapy application will be utilized.

1. Non-adherent dressings are applied to the wound to create a barrier [19]. Some materials to take in consideration are Adaptic [20], Mepitel [21], and petroleum gauze [22].

2. Polyurethane foam is utilized to fill the wound cavity, ensuring vacuum pressure is evenly distributed [23].
3. A thermoplastic polyurethane film can be applied to secure the foam, creating a sealed environment [24].
4. Alternatively, hydrocolloid dressings can be utilized in conjunction with NPWT devices. Hydrocolloid dressings contain a gel-forming agent and tend to be more flexible than foam [23].

k. **Aesthetics, Appearance, and Finish**: Color, shape, form, and texture of finish should be specified where possible (get opinions from as many sources as possible).
    i. Due to the innovation of the design idea, the shape, color, form, and texture of the finished device will be up to the client's discretion.
        1. In rhytidectomies, incision cuts are located around the ears and along the hairline [25]. To ensure variability, the HeadVac will extend over the ears. The shape of the design can surround the head circumference, covering the hairline and ears. Alternatively, the device may extend over the ears and along the hairline, but not extend inferiorly past the incision cuts on either ear.
        2. Dressings and device application will occur at the end of the rhytidectomy procedure. The color of the device will be a neutral tone. Due to the Code of Federal Regulation, Title 21 [26], neutral tones are required in operating rooms [27].
        3. The client has requested a comfortable material and texture for patients. The texture must be soft, adaptive, and supportive.

2. **Production Characteristics**
    a. **Quantity**: number of units needed
        i. The target prototype accounts for all head sizes with the integrated negative pressure system attached to it, in addition to the dressing. This would enable the user, no matter the demographic, to be able to purchase and use one singular product

    b. **Target Product Cost**: manufacturing costs; costs as compared to existing or like products
        i. The client has given the team a budget of $1000 to develop a prototype. The entire device can be split into 3 major components: the gauze/dressing, the fluid container, and the negative pressure system.
        ii. The Gauze/dressing and the fluid container retail for as low as $5.00. The headband containing the gauze and tubing is what the team is developing, for which $400 will be allocated for the development. Cost includes purchasing materials, sensors, and manufacturing costs of the headband.
        iii. The team is not required to build a new NPWT unit. On the market, full-fledged units retail from $300 to $2500. The team plans on allocating upwards of $500 to purchase a unit.
        iv. The most common sales model for an NPWT system is a rental model, with prices upwards of $25.00 per day [28].

3. **Miscellaneous**
    a. **Standards and Specifications**
        i. This medical device will likely be listed as a class II medical device. This is due to the device's direct interaction with the body, but its lack of use in life-sustaining applications. The device will likely require a 501(k) premarket notification [29].
        ii. ISO 10993: The device must comply with this standard to meet general safety requirements for medical devices. The device will be analyzed according to this standard to ensure general safety and fitness for use in its applications [30].
        iii. ISO 11135/11137: The device must comply with standards relating to ethylene oxide (EO) sterilization or radiation sterilization, depending on the optimal sterilization technique used by target hospitals. If the device is disposable, this standard is not a concern [31].
        iv. ISO 13485: If the device is eventually manufactured in mass, it must comply with relevant standards for quality and safety during use as it relates to its manufacturing processes [32].
        v. ISO 14971: This standard helps identify risks and hazards associated with medical devices. This standard specifies that the medical device's manufacturer must establish objective criteria for risk acceptability as it pertains to the medical device [33].
        vi. IEC 62366: Because of the particular, nuanced, and skillful nature required to successfully apply NPWT, the device should be analyzed according to IEC 62366 to determine its usability in relation to safety. This standard will assist in identifying risks in correct use and in erroneous use of the device [34].

    b. **Customer**: Specific information on customer likes, dislikes, preferences, and prejudices should be understood and written down.
        i. The client does not have any specific likes, dislikes, preferences, or prejudices restricting the design of the device. The device should be adjustable, disposable, and be applicable to multiple rhytidectomy incision locations.

    c. **Patient-related concerns**:
        i. Patient-related concerns are up to the surgeon's discretion, as rhytidectomies are highly individualized [35].
    d. **Competition**: Are there similar items that exist (perform a comprehensive literature search and patents search)?
        i. <u>NPWT in Head & Neck</u>
            1. There are medical reports and studies using NPWT for wounds in the head/neck region. For example, *"Negative Pressure Wound Therapy in the Head and Neck"* (PMC) discusses use of standard NPWT with adjustable negative pressure, dressings, etc., in this region. [36]
            2. Also, Negative Pressure Wound Therapy in Head and Neck … shows use of foam sponges, occlusive dressings etc., for facial wounds.
        ii. <u>Patents / Devices for NPWT</u>
            1. **US8663198B2**: A flexible housing with a gasket, port, non-woven absorption material, wound interface layer; foldable housing for appendages, with improved sealing mechanisms. [37]
            2. **US-11471585-B2**: A negative pressure wound therapy device / system / method. The details differ depending on embodiment. [38]

3. **US-7534240B1**: NPWT system combining the foam pad with introduction of wound-healing agents (e.g. growth factors). [39]
4. **US-9962295-B2**: A wound closure device via negative pressure.[40]
5. **US-11896465-B2**: Smith & Nephew patent for device activation/control in NPWT (likely includes safety features, sensing, etc.)

iii.

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