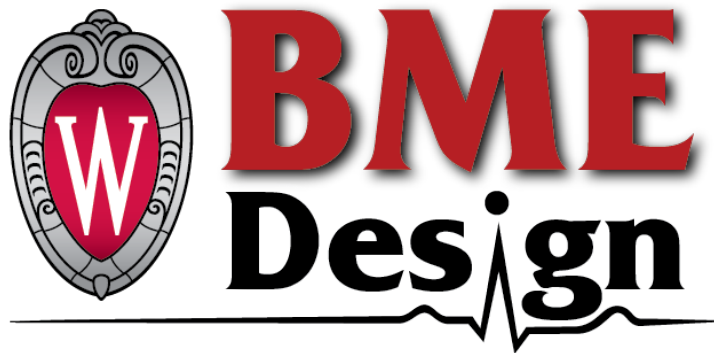




OstoSeal

Product Design Specifications

Section 311

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Function

This project will work towards the creation of a safe, comfortable and effective ostomy pouch and wafer adhesive cover meant to keep the two components dry during showering. Current methods of keeping ostomy pouches and adhesives are often unreliable or inconvenient which negatively impacts the users quality of life. This cover is intended to work with a schedule of at least daily showers, and must be durable and easy enough to use in order to accommodate this stipulation. This device should be firmly waterproof and compact to support a schedule of daily use. Also, it must fit the variety of pouch sizes and waistline shapes and sizes that a person could have.

Client Requirements

- The device must keep all portions of the ostomy bag dry for the duration of a 5 to 30 minute shower.
- The device must be able to be used daily.
- The cover must be reusable for 6-12 months.
- The device must not encircle the waist.
- The device must be flexible and contact a minimal amount of skin.
- The device must not put any portion or working of the ostomy bag in danger of being damaged.

Design Requirements

1. Physical and Operational Characteristics

a. Performance Requirements

- i. The device must be able to endure daily use in the shower for 6-12 months, excepting the disposed adhesive, which can be replaced for each shower. It must be waterproof and resistant to damage caused by soaps.
- ii. The device must stay in place through moderately active movement while the user is showering, and should be able to handle minor incidental jostling.
- iii. The device must be completely compatible with an ostomy bag; under no circumstances should the device interfere with the performance of the user's ostomy bag.

b. Safety

- i. Under Standard ISO 10993-1, the adhesive used to attach the device to the user's body must be tested for biocompatibility with skin [1]. More information about this standard can be found in "Standards and Specifications".
- ii. An ill-fitted ostomy bag cover can cause pinching and prohibit the bag from performing properly, potentially leading to hazardous consequences [2]. OstoSeal must therefore ensure there is sufficient space under the cover for an ostomy bag at its largest expansion.

c. Accuracy and Reliability

- i. The device must endure at least six months of use without any damage or change in performance.
- ii. When a new adhesive is attached to the device, it must consistently endure a shower of at least 30 minutes without slipping or leaking.

d. *Life in Service*

- i. The device should be designed for repeated use during regular showering. The reusable components should withstand repeated exposure to moisture and warm water, soap, shampoo, and other products the user regularly comes in contact with while showering. The client has indicated that the waterproof cover itself should be reusable, while the adhesive component may be disposable or replaced between uses. The reusable cover should maintain its intended functionality, waterproofing performance, and material integrity for at least 6-12 months under recommended use, cleaning, and storage conditions.

e. *Shelf Life*

- i. The reusable OstoSeal cover should last 6-12 months of regular use, and should be stored in a clean and dry environment. Between uses, the apparatus should be laid out or hung up to allow the product to fully dry after use.
- ii. Each sheet of silicone tape adhesive is reusable for up to 7 days with proper maintenance, that is, being gently washed in warm water and air dried. The adhesive roll given to the client should be able to be stored for at least one year before needing to be replaced [3].

f. *Operating Environment*

The device should be designed to operate in a typical shower environment. During use, it may be exposed to warm water, assuming average warm shower temperatures ranging from 33.0°C to 44.0°C (approximately 91.8–111.2°F) [4]. It may also be exposed to high humidity, steam, soap, shampoo, body wash, and other common personal hygiene products.

g. *Ergonomics*

The device will encircle the ostomy bag and stick to the skin with adhesive tape. The tape will be peeled and applied around the edges of the device before each use, then removed following the use. It should stay firmly adhered to the skin throughout the entire - 5 to 30 minute - duration of use while under continual water contact. The main cover material should be nonabrasive to the skin and unobtrusive in size and shape. It should be small and flexible enough to not pose unnecessary discomfort or harm during the usage period.

h. *Size*

- i. Standard to large ostomy pouches range in length from ~8-12 inches. The width of the adhesive/opening portion can range from $\frac{3}{4}$ " to 4"[5][6].
- ii. The cover should not include excessive extra material but should accommodate different size ostomy pouches and the possibility of growing dimension as it fills.

- iii. The product should not fit tight enough to the ostomy bag that application and removal is hindered.
- iv. The product should be ~14 inches in length and ~6 inches in width.

i. Weight

- i. A reference waterproof ostomy shower cover has a weight of approximately 85 g [7].
- ii. The final device should have a maximum weight of 100 g.
- iii. The device should not retain a significant amount of water during use to minimize additional weight during showering.

j. Materials

- i. The cover material must be waterproof and resistant to common soaps and body washing products.
- ii. Materials that contact the skin must minimize irritation and damage to the skin. Medical adhesive-related skin injuries can include skin stripping, tears, irritation, and other forms of skin damage [8].
- iii. Materials and adhesives should minimize moisture accumulation against the skin, as prolonged moisture exposure can cause increased susceptibility to skin injury [8].
- iv. Materials should be sufficiently flexible to conform to variations in abdominal contours and pouch sizes while maintaining a waterproof seal [8].
- v. The cover should be reusable and maintain its material properties following repeated exposure to water and soap.
- vi. Adhesive components may be disposable if a reusable adhesive is not feasible or cost-effective, as specified by the client.

k. Aesthetics, Appearance, and Finish

- i. The finished device should have smooth surfaces and edges to prevent scratching, irritation, or damage to the user's skin, ostomy pouch, or wafer.
- ii. The device should minimize unnecessary bulk around the ostomy pouch during use.
- iii. The cover should maintain a clean and discreet appearance appropriate for a personal medical device used on a daily basis.
- iv. Aesthetic features should not interfere with the device's ability to form and maintain a waterproof seal around the ostomy pouch and wafer.

2. Production Characteristics

a. Quantity

The final design will include one showerproof ostomy bag and a roll of adhesives. The showerproof ostomy bag can be reused, but the adhesives will have to be replaced after every use. Providing the client with a roll of adhesives will allow for multiple applications before they run out.

b. Target Product Cost

As per the client, there is not a set budget for this project, but the total costs are estimated to not exceed \$100 based on preliminary research. Money will be allotted to cover all the raw materials for the adhesives and the waterproof ostomy bag shower cover. Additional costs may include filament for 3D printed prototypes, if needed. Only the materials listed above will count towards the budget, whereas any equipment or facilities used will be excluded. Existing showerproof ostomy bags cost anywhere from \$19.99-\$45.58 for the entire contraption[9], and the final design will likely be on the lower end of that range.

3. Miscellaneous

a. *Standards and Specifications*

The product will need to comply with Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" [10]. The materials that we are considering for the cover are outlined in Section B of Attachment G [11]. However, due to the adhesive of our product, as outlined in Table G.1 Exclusion Characteristics, our product would need to undergo traditional biocompatibility testing. Per Part 876.5900 of Title 21, Chapter 1, Subchapter H, this product is exempt from the premarket notification procedures in subpart E of part 807 of this chapter [12][13]. For feedback or meetings regarding medical device submissions, the Q submission program can be used [14][15].

b. *Customer*

- i. The product should cover minimal skin surrounding the stoma for comfort and to allow for bathing as much of the body as possible.
- ii. Belt designs are disliked as they do not adhere to the above criterion and have varying performance in staying fully waterproof.
- iii. The product should be easy to store.
 1. Belt designs are larger and stay wet for longer as parts of the belt may absorb water making them less desirable.

c. *Patient-Related Concerns*

The device must keep both the covering and adhesive portions of the ostomy bag dry under continual contact with water. It must be flexible in order to be easily maneuvered around. It also must be compact and contact a minimal amount of skin to ensure user comfort. In addition to this, the device must be able to be taken on and off quickly and easily, and not cause excessive pain during adhesive removal.

d. *Competition*

The main forms of ostomy bag waterproof covers on the market are belts, adhesive pouches, and adhesive patches. Belts are very prevalent, most of which employ a flexible bag cover attached to an adjustable strap that fastens around the waist. YEYSXSY advertises a belt where the ostomy bag is tucked into a thin cover that lies flat against the stomach [16]. This belt reportedly keeps the ostomy bag and its adhesive from getting wet, but is uncomfortable for individuals without flat waistlines. The adhesive patch is

also common, with EveryMarket advertising large squares of adhesive that have gauze-like material in the middle to keep the ostomy bag from getting stuck. This product received a majority of reviews reporting effective waterproofing, but came with complaints on the excessive stickiness of the material [9]. Pouchwear avoids this issue with a pouch that simply elastically holds itself around the ostomy bag [17]. However, this product does not keep the adhesive around the ostomy bag dry. A firmly attached, comfortable, and painless waterproof cover is needed to effectively keep both the adhesive and bag around the ostomy dry.

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