# Device to Assist Pill Removal from Bubble Wrap Packaging

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# **Abstract**

A common trait of the elderly population is decreased hand strength and dexterity. This is a condition which advances as people age. Additionally, the elderly population takes numerous pills which come in a variety of different packages. One type of packaging is called blister packaging. Due to decreased hand strength and dexterity, these blister packages are hard for the elderly to open. The goal of this project is to create a device which makes the process of opening blister packaged pills easier for the elderly population. The device will be an extremely safe device which is ideal for home use by the patient. Furthermore, the device should not require assistance to use and should not damage the pills in any way. The final design which is presented in this paper incorporates all major requirements through the use of a concealed blade and low friction track. A safety mechanism will be utilized for increased safety. Future work for this project will focus on a solid construction of the device followed by initial and field testing of the device.

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#### **Problem Statement**

Many over-the-counter medications are packaged in blister or bubble wrap packaging so that individuals or their caretakers can easily determine the number of pills taken in a given period of time. However, it is difficult for individuals with decreased hand strength, especially the elderly, to remove medication from this type of packaging. These difficulties lead struggling patients to alternative access methods that are often dangerous. It has been proposed to design a device capable of aiding patients in the removal of over-the-counter medication from blister pack style packaging.

## Introduction

Hand Strength and Aging

With age comes vulnerability to chronic diseases like rheumatoid arthritis, stroke, Parkinson's disease, cognitive impairment, and impaired vision <sup>[1]</sup>. In addition, decreases in dexterity and overall strength promote the lack of independence with elderly groups <sup>[2]</sup>. These disabilities in combination or alone make even the most everyday tasks more difficult for the elderly. These tasks can be as trivial as tying a shoe, or preparing a sandwich, or as important as removing medication from packaging.

Although decreases in strength and dexterity affect most muscles in the body, one of the most important areas of concern is the hands. Most of the general activities preformed throughout the day either require dynamic gripping or manual manipulation <sup>[3]</sup>. Age brings about a significant decrease in strength of the hands <sup>[2]</sup>. Figure 1 illustrates the results of a study in which two groups, old and young were put through a variety of motor tests involving their hands.

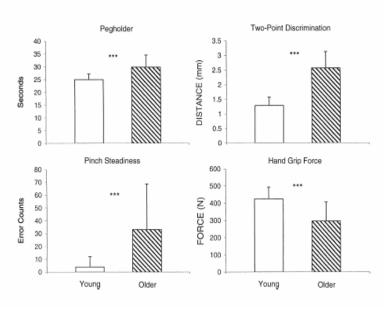


Figure 1: Comparison of young vs. old groups in their performance of simple hand related tasks [1].

As noted by the bar graphs, the older groups displayed significantly less grip strength than younger groups and also failed to hold their hands steady. In addition they exhibited less sensitivity, dictated by the two point discrimination experiment.

All of these results translate to one

fact: aging has a degenerative effect on hand function [1][3].

While decreased sensitivity does not have a major affect on the design of the device, it does illustrate the fact that the nervous system in older individuals tends to decline. This will have an effect on the design because of central command fatigue. Central command fatigue occurs when the central nervous system (CNS) stops recruiting motor units (even though there are still motor units to recruit) [4]. Thus, in elderly individuals with a degenerating nervous system, central command fatigue may set in earlier resulting in a decreased overall force produced. This is not the main reason for decreased strength in the elderly; however, it does contribute to it making it relevant to this project.

When taking into account the design of this device, it is important to be able to quantify the maximum amount of force which the device can require. The study performed by Frontera, W.R. et al. states that "28% of elderly men and 66% of elderly women cannot lift objects weighing >4.5kg". Thus, when designing the device it is important to not exceed a required force of 4.5kg (~10 pounds) <sup>[5]</sup>.

The decrease in strength is primarily due to decreased muscle mass; however, central command fatigue may play a role as well. Dr. Ranganathan and colleagues state, "it has been reported that a 15% loss in strength per decade occurs in 50 to 70 year old individuals." He also states, "...there is a 50% decline in strength associated with a 40% decrease in skeletal muscle mass between the ages of 50 and 80 <sup>[1]</sup>."

With age, comes the requirement for more medication to cope with the variety of health issues that can present themselves to the elderly. These medications come in many different

forms with pills being the most popular. Of these, overthe-counter (OTC) medications are the easiest form of drugs to obtain, as no prescription is required. These OTCs are usually packaged in what is called blister packaging (Figure 2). Although, blister packaging may seem convenient to those who are able to open it, it poses problems to the elderly <sup>[6]</sup>.



Figure 2 - Several examples of blister pack style packaging (http://images.jupiterimages.com/common/detail/05/91/22189105.jpg)

A study conducted in Stockholm, Sweden found

that 10% of the elderly have trouble with opening medication in blister packaging. The researchers concluded that, "...[the] ability to open medicine containers is impaired by several conditions affecting physical and cognitive functioning." Furthermore, of the subjects who were unable to open the medication, 27% of them live at home and receive no assistance in the opening of blister packs. These subjects who live by themselves could potentially hurt themselves when searching for alternative methods to open the medication <sup>[7]</sup>. Therefore in this case, an assistive device for opening blister packaged medication is not only ideal, but it is necessary.

## Current Devices

There are a number of patented devices that have been designed in an attempt to aid patients in removing pills from blister packaging however, these devices do not properly address all of the problems related to removing blister packaged pills. As stated previously, elderly patients have decreased hand and grip strength making many of the current devices insufficient for this particular user group. To illustrate this, consider the device described in U.S. Patent

5,722,563 (Figure 3) [8]. This device requires significant grip strength *and* hand dexterity to operate. Studies above illustrated that elderly patients exhibit decreased hand strength as a result of decreased muscle mass and

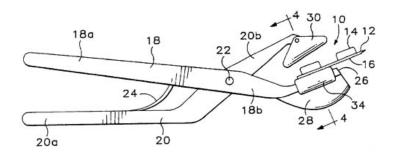


Figure 3 - Pliers style device for forcing pill through blister pack (U.S. Patent 5,722,563)  $^{[8]}$ .

central command fatigue <sup>[2][4]</sup>. For this reason alone, this device is unusable by the group of patients which are targeted by this project.

Another aspect that most current devices do not address is peel away packaging.

Numerous pills are packaged using blister packs which have a thin lining which must be removed before the pill can be removed. The device in the previously mentioned patent does not address this, thus, ignoring a large portion of the over the counter pills on the market. The target patients for this project would likely have difficulty removing the peel away layer making the aforementioned device insufficient.

The device described in U.S.

Patient 4,909,414 attempts to address peel away packaging; however, it is designed primarily for the mass opening of blister packaged pills (Figure 4) <sup>[9]</sup>. Furthermore, the device is not designed with safety in mind. Insufficient safety considerations

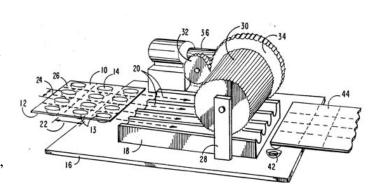


Figure 4 - Blister pack pill removal device which takes peel away packaging into account (U.S. Patent 4,909,414) [9].

as well as bulk opening are two factors which make this current device unsuitable for this project's target patient group. This particular device uses a blade which slices between the pills and the peel away layer of the blister packaging to dispense the pills. The device rolls an entire sheet of blister packaging over the blade opening all pills at the same time. While this device is great for someone like a nurse or pharmacist to use in a hospital setting, it is not an acceptable device for a patient to use in their home. The open gears and motor make it unsafe for home use.

In addition, opening all pills from a blister pack at once is undesirable because blister packs are designed to ensure that patients can keep track of the medication they have taken.

One last device to consider in detail is the device which is presented in U.S. Patent 5,405,011 (Figure 5) <sup>[10]</sup>. This design is a hand held device which dispenses pills each time its top is pressed down. The device implements an intricate

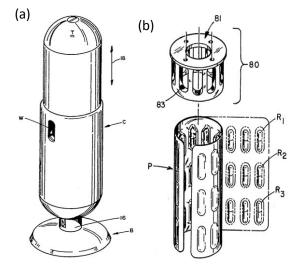


Figure 5 - (a) Hand-held cylindrical blister pack pill dispenser (U.S. Patent 5,405,011) (b) Complicated inner workings of the cylindrical pill dispenser require specific pill spacing as well as an intricate setup procedure (U.S. Patent 5,405,011) [10]

mechanical system which would be extremely hard for an elderly person to use. A study above shows that elderly patients exhibit decreased pinch steadiness, illustrating the difficulties this device would pose to the elderly [1]. The device requires blister packaged pills to be wrapped around an inner cylindrical core. This task would be tough for the target patients of this project. Furthermore, the dimensions of the device require the blister packaged pills to be of a certain size, and spaced at a particular interval (Figure 5). For these reasons, this particular device does not meet the expectations of this project. After considering each of these current devices as well as meeting with the project's client, the design team has developed specific design criterion to consider in while developing this device.

# **Design Specifications**

In order to obtain functionality and safety, the pill removal device must be designed according to a number of specifications set forth by both the client and the design team. The primary requirement for the device is that it must aid patients in the removal of medication while requiring minimal hand or grip strength, as well as minimal steadiness and dexterity. The design team is aiming at creating a device which requires less strength than it would take to open a car door. The device should be controlled using a button or handle that is large and easy to maneuver. Another major requirement is that the device must pose absolutely no threat to the user. In addition the device must be designed so that it is compatible with a wide range of pill packages. This includes pills in both "punch out" and "peel away" blister packages that come in a wide variety of shapes and sizes. It is also important that the device leaves the pills unharmed in the process of removal. Finally, the first generation prototype will be designed primarily for home use; therefore its size should not exceed that of a countertop appliance with an estimated

volume of 216 cubic inches. It should also be easily transported from room to room weighing no more than five pounds. The allotted budget for this project is \$1000, but the design team is confident that a working prototype can be developed for less money than that.

# **Design Alternatives**

# Design 1: Linear Punch

The linear punch design
incorporates a linear actuator which
would be used to mechanically punch
pills out of their blister packaging. A
linear actuator is a device that uses a
small electric motor to linearly eject a
small metal rod out of a shaft (Figure 6).
The actuator would be fixed above a
platform where the pill packaging would
rest, and would eject its metal rod

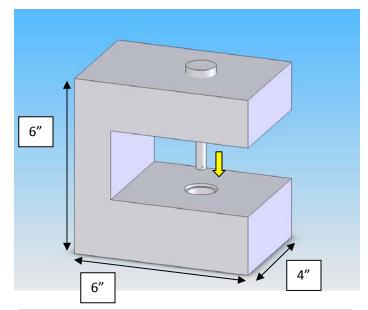


Figure 6 - Linear punch design utilizes linear actuator to punch pills out of their packaging

pressing the pills out of their packaging. The platform would require an opening for the pills to be dropped into once they are punched from packaging. Because pills come in various shapes and sizes, the opening in the platform would need to be either big enough for the largest size pill or include a method to change the size of the opening for different pill types. This method of changing the opening would require inserts that would fall into place in the previously mentioned platform opening. Below this opening, a tray or retrieval cup would be used to collect the pills after they were removed from their packaging. The platform containing the opening as well as

the collection mechanism would be built into a base constructed from either rigid plastic or thin metal sheeting.

Because the patients that are going to be using this device have limited strength, a push button would be used to electronically initiate the working of the actuator. Once the button was pressed the linear actuator would eject the rod towards the pill on the platform. The linear actuator would be programmed so that the rod would eject down onto the pill and retract back into the shaft once the pill was removed from the package. A safety mechanism, such as a cylindrical cage surrounding the punch out area, would be incorporated to ensure that the actuator rod couldn't cause harm the user.

One major advantage to this design is that it requires virtually no strength from the user to initiate the actuator, only the push of a button. In addition, the device could be made small enough to easily fit on a countertop, and be transported within the home. Also, if constructed properly, the device would be very safe for the user. The major disadvantage to this device is that it is unsuccessful at opening "peel away" blister style packaging. Because the peel away packing is made out of stronger material, the actuator would crush the pill instead of removing it from the packaging unharmed. This greatly reduces the variety of packaging this design is compatible with. In addition the use of a programmed linear actuator would increase the cost of the unit significantly.

# Design 2: Rolling Punch Design

The rolling punch design is very similar to the linear punch design but incorporates an additional piece which aides in the removal of the pill from its packaging. Like the linear punch design, the rolling punch would utilize a linear actuator mounted above a platform where

the pill packaging would rest. Instead of the linear actuator punching the pill out

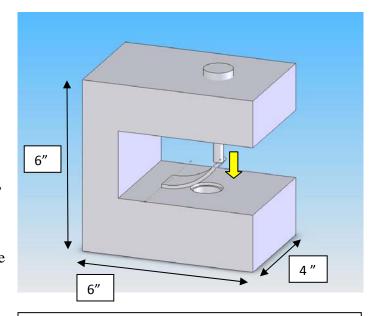


Figure 7 - Rolling punch design utilizes linear actuator in conjunction with thin, bent piece of metal to punch pills out of their packaging

of the packaging directly, it would be fixed to one end of a curved piece of thin metal. On its other end, this curved piece of metal would be fixed to the platform on which the pill packaging would rest (Figure 7). As the linear actuator's drive rod was extended, it would press the unfixed end of the curved piece of metal towards the platform, and in the process roll the curved metal across the pill packaging removing the pill. Like the linear punch design, the pill would be pressed through a hole in the platform and collected in a collection dish or drawer which would be incorporated into the base. The actuator would be programmed to retract after the pill was removed from its packaging. Again, different sized inserts would be utilized to ensure the device worked on a variety of pill sizes and shapes.

The advantage of incorporating this rolling mechanism into a punch design is that it would require the actuator to generate much less force. Since the curved piece of metal rolls across the pill, one edge of the pill would be pressed through the packaging first and then the rest

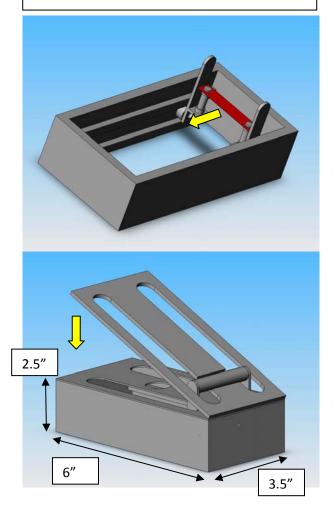
of this pill would follow. This rolling punch mimics the way a patient would bend the pill packaging, pressing the sharp corner of the pill through first before pressing the rest of the pill through. One of the major advantages of this design is it would require only enough strength to press a button which would control the linear actuator. Another advantage is the device could be designed to be compact and could fit nicely on a countertop. Like the linear punch, the disadvantage of the device is it is unable to remove pills from peel away packaging. Since the backing on this packaging is quite sturdy, it is likely that the rolling press would crush the pill, which is unacceptable by the client. Also the linear actuator used in this design would raise the price of production, something that the design team hoped to avoid.

# Design 3: Concealed Blade Design

The concealed blade design is a device utilizing a thin blade that is concealed from the patient during use and is used to cut through the packaging to remove the pill. When incorporating a blade into the design, the safety of the patient must be the first consideration. This device utilizes a blade, similar to that of a cigar cutter, to slice away the back of the packaging without damaging the pill or causing harm to the patient.

The base of the design is the most intricate part, requiring many small parts that will work

Figure 8 - (a) Concealed blade design without base top and clamp layers (b) Complete concealed blade design with base top, rotating clamp layer and handle



collectively to slide the blade. The base would be constructed from rigid plastic and would be glued together using a strong adhesive such as epoxy. The platform of the base would be comprised of very thin sheet metal and would also be glued on top of the plastic walls. Two cuts would be made into the platform, the opening where the pill packaging will sit face down as well two slots that will allow a blade located under the platform to be slide back and forth from above. To allow the blade to cut through the packaging without damaging the pill, it would be placed tightly against the bottom of the platform and still allow effortless movement. Nuts and bolts would be used to hold each end of the blade up, allowing height adjustment of the blade. These bolts would be attached to a T-bracket which would be fastened to two small drawer slides providing the mechanism for the controlled movement of the blade (Figure 8). The upper end of each of the T-brackets would be connected together by a handle used to slide the blade back and forth.

To conceal the blade during use and clamp down the pill packaging for cutting, another metal or plastic layer would be included above the platform where the packaging sits. To allow the slide mechanism to work without interference, two slots similar to the slots in the platform would have to be cut into this upper layer (Figure 8). A rubber material may be added to the bottom of this layer to hold the packaging in place while the blade passes through it. To make sure this layer doesn't move during use, a latch would be included which would firmly hold it closed. A simple front latch could be used that would hook the upper layer to the base and could be easily released. This will ensure the security of the patient and the pill during use.

A safety mechanism would have to be incorporated into the device so that the blade could not come into contact with the patient while the upper platform is open. A latch could be used to hold back the blade while the platform is open; ensuring that the blade remains in its position and

the user is unable to slide the handle forward. Suction cups could also be positioned on the bottom of the base to attach the base to a countertop so that the device would require one hand to operate and thus less dexterity. A cup or retrieval tray would be used on the bottom of the base to allow easy access to the pill after it has been removed from its packaging

A major advantage of this device is that it allows the patient to use it for a broad range of pill packaging. Different size holes could be used for different size packaging. Unlike the other two designs, this device is capable of opening both "punch out" and "peel away" packaging. The safety mechanism will also keep the patient safe during use. Also the device should be rather inexpensive to produce. One problem that may occur with this device is that some packaging has limited space between the pill and the package, so pill damage may occur.

# **Design Matrix**

To evaluate each of our designs we developed a design matrix which incorporates the major requirements for this project. Because some requirements were deemed more important than others each requirement was weighted on a scale from zero to one with the total of all weights adding to one. The requirements considered were user safety, effectiveness, pill safety, ease of use, and package variety. The user safety was assigned the highest overall weight of 0.25 because the design team, along with the client, felt that this requirement was the most important. The effectiveness, pill safety, and ease of use categories were each assigned weights of 0.2 because the design team felt that each of these categories was an integral part of the design. However, these categories were given a weight less than that of safety because the design team unanimously concluded that user safety should never be compromised solely to improve in one of these other categories. The category of effectiveness takes into account how well the pill is

removed from the packaging. A device which is highly effective would be able to completely remove a pill from the blister packaging each time the device was used whereas a device which is not highly effective may only be able to partially remove the pill (by slightly tearing the underlying peel away or punch out layer) or remove it only half of the time. The pill safety category considers how much damage may be done to the pill upon removal. For example, a gel cap may be squished by the linear punch design which would likely result in discarding of the pill. This category is also important when considering extended release pills. These pills are designed to release the drug over an extended period of time. If the pill is damaged, the patient may receive the pill's entire dose at one time which can be dangerous. The ease of use category is fairly self-explanatory as this device will need to be easily used by elderly patients and patients with decreased hand strength. Finally, the package variety category was assigned a weight of 0.15. The design team felt that this category was least important for the initial design of this product. At this point, it is more important to design a device which satisfies all other requirements. The device can be adapted to numerous different pill sizes and shapes in the future.

Each of our designs was assigned a rating of one, two, or three depending on the designs performance in the particular category. A rating of three indicates superior performance, two indicates fair performance, and one indicates poor performance for a given category. Each design was scored by multiplying its rating in each category by the category's weight. The results for each design were tabulated, and the concealed blade design came produced the highest score of 2.55. The rolling punch design achieved a score of 1.80, and the linear punch design came out with a score of 1.70. We will pursue the concealed blade design during the rest of the semester.

	Weight	Linear Punch	Rolling Punch	Concealed Blade
User Safety	.25	3	2	2
Effectiveness	.2	1	2	3
Pill Safety	.2	1	1	3
Ease of Use	.2	2	2	2
Package Variety	.15	1	2	3
Total	1.00	1.70	1.80	2.55

Table 1 – Design matrix for design alternative evaluation

## **Future Work**

After the decision to pursue the concealed blade design, the future of this project begins with attaining the parts necessary for prototype construction. The major parts that need to be ordered are plastic materials for the base, a drawer slider, sheet metal for the platform, Tbrackets, nuts and bolts, and the blade. The drawer slides have been purchased from an online retailer of small home furnishing parts called Alema Inc. The part chosen was a Sugatsune ball bearing drawer slide costing approximately \$40. Metal sheeting for the platform and plastic for the base will be obtained from McMaster-Carr costing around \$40. Nuts and bolts will be purchased from a local hardware store and should cost no more than \$5. It is likely that the tbrackets will need to be custom fabricated from the metal sheeting as their odd shape makes them unlikely to be readily available. Finally, a package of microtome blades can be purchased from the Cresent Manufacturing Company for roughly \$30. The fabricating process could possibly be completed in a one to two week period if all of the parts fit as we have them pictured. Upon finishing the device we would like to test it ourselves and adjust it so that the blade cuts through the packaging with the least effort. We would like to test the device using various pill packaging and record how efficient the device is with different types of packaging and whether or not the device does harm to the pills. This can be done by purchasing a variety of pills in

different sizes and shapes and using the device to remove them, recording how complete the removal was after one attempt. For example, the pill could be completely removed, or the packaging could only be separated halfway. We would also measure the extent of the physical damage to the pill. Physical damage could be quantified by weighing the portion shaved off by the blade and comparing it to the mass of the pill before removal. We also want to test to make sure no physical injury can be caused to the user in any circumstance. Once we all agree that the device works correctly and safely we would like become approved by the IRB for human subjects testing and run tests using elderly patients. We would like to get their feedback on how they like the device and anything that they would recommend to increase usability. Changes may be done to the device as problems occur and further testing will be done until patient problems are minimized. Once the workings of the device are final, we can improve the aesthetics of the device and possibly begin to market the device.

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# **Appendix A: Project Proposal**

# 29. Device to Assist in Removal of Pills from Bubble Wrapped Packaging Benjamin Engel, Ryan Carroll, Justin Schmidt, Eric Printz

# **Qualifications:**

The proposed Pill Removal Device project is an excellent fit for us as its parameters align well with our strengths as engineers. A Pill Removal device will likely include two major components, a mechanical aspect used to physically remove the pill from the packaging, as well as an electrical component used to control the mechanical design. Our designs could therefore require the use of a microcontroller and a linear actuator. This is convenient in that one of our members participated in a microcontroller seminar. As a team we have demonstrated our strength and understanding of mechanics through both coursework and previous design projects. The microPET/CT heating device which we all worked on together in the spring of 2007 required fabrication of custom design parts. In fall of 2007 Ryan and Ben demonstrated strengths in fabrication while designing and constructing an interface for their adjustable wave tube stand. In addition our members have gained experience with electronics and circuitry from the microPET/CT project as well as the nighttime weight-change measurement project.

#### **Motivation:**

Our motivation for this project stems from the fact that it will require us to incorporate electronic control to a mechanical device. In previous semesters we have worked on projects that were limited to only one or two feasible design alternatives. We feel that with this project we will be able to develop and evaluate an abundance of designs. This project requires work in the field of human factors and ergonomics both of which are strong areas of interest for the members of our group. As a group we are excited at the prospect of working with disabled patients in the testing phase. Furthermore, we have multiple members that are focused on the field of industrial systems engineering and are very excited to have the opportunity to work with an expert in this field, Dr. Molly Carnes. In previous semesters our members have developed products to be used primarily in the research field. We feel that this project could result in a marketable device that is applicable to a large population. Throughout the semester we hope to develop and improve a number of design process skills. Of major concern to this group is the development of excellent client relations, something that has been lacking in previous projects. We also hope to advance our skills in the fabrication shop as well as improve our understanding of electronically controlled devices. We are confident that combination of qualifications as well as interest in the specific project makes our team an excellent fit.

#### **Appendix B: Product Design Specifications**

# Device to Assist in Removal of Pills from Bubble Wrapped Packaging

Client: Dr. Molly Carnes MD, MS, Professor, UW Center for Women's Health Research

**Advisor:** Professor Brenda Ogle, Ph.D.

Team: Benjamin Engel, Leader

Ryan Carroll, Communicator

Eric Printz, BWIG

Justin Schmidt, BSAC

#### **Problem Statement**

Patient safety issues involving the improper use of medication has lead to packaging of over the counter drugs that is increasingly difficult to access. This type of packaging is referred to as blister pack or bubble wrap style packaging and it is especially challenging for elderly patients with decreased hand strength or others with hand weaknesses or deformities. These difficulties lead struggling patients to alternative access methods that are often dangerous. It has been proposed to design a device capable of aiding patients in the removal of over-the-counter medication from bubble wrap style packaging.

#### **Client Requirements**

The prototype must be designed to meet the following requirements set forth by the client

- Device must require little hand strength
- Device must be able to remove a variety of over the counter drugs which vary in size and shape
- Device should be able to open punch out blister packaging and peel away packaging
- Device should be designed to fit on a kitchen countertop
- Device can contain no exposed blades or mechanisms that may be dangerous to elderly users
- Device must leave pills unaltered following removal from packaging

#### **Design Requirements**

#### **Physical and Operational Characteristics**

- a. *Performance requirements:* The pill removal device must provide adequate assistance in removing pills from difficult packaging while requiring little hand strength. Device must remove pill from packaging unharmed and should require no more than one attempt to remove. Pill should be delivered to a location where it is easy for the patient to pick up and take the pill.
- b. Safety: The device should contain absolutely no sharp edges or exposed blades and should be designed to minimize the potential of injury due to pinch in mechanical/moving parts. If moving blades are to be incorporated, a safety mechanism must keep them unexposed throughout use.
- c. Accuracy and Reliability: This device should be capable of opening the pill on the first trial. It should also be designed such that it is easy to configure (align pill packaging with removal device). Device should not cut, crush, or shave the pill, or alter it in any manner.

- d. Life in Service: If used properly, this device should not have a limited life in service, barring any unforeseen electrical or mechanical malfunctions.
- e. Shelf Life: The pill removal device will likely be stored on a kitchen/bathroom countertop or closet. If stored in a safe environment, the shelf life of the device should be unlimited. There is potential for the device to become defective if contacted with any outside agents such as water or cleaning solution.
- f. Operating Environment: The first generation device will be designed primarily for home use.
- g. Ergonomics: The device should be designed according to human factors and ergonomic principles. The product/user interface should be designed for comfort and ease of use, keeping in mind the age of the projected user. All adjustment controls should be large and very simple to use. In addition any instructions to be printed on the device should be written in large font with significant contrast making them easy to read for the elderly user. It may be important to consider anthropometry in later generations.
- h. Size: The device should be designed to fit on a countertop and be easily stored in a household closet.
- i. Weight: Device should be designed such that it is easily transported by an elderly user from room to room within his or her own home.
- j. Materials: Materials used for this design should be non-hazardous, lightweight and durable.
- k. *Aesthetics*, *Appearance*, *and Finish*: Device should be aesthetically appealing in a home kitchen or bathroom setting.

#### **Production Characteristics**

- a. *Quantity*: Initially one prototype will be constructed, however there is potential for mass production if device is deemed patentable.
- b. *Target Product Cost*: The cost of the device should not exceed \$1000, however the design team is confident that a working prototype can be constructed for far less money than that.

#### **Miscellaneous**

- a. Standards and Specifications: This product is not required to meet any standards put forth by an outside organization. All requirements are specified above, and have been provided by the client.
- b. *Customer:* The target customer for this device will be primarily elderly patients with decreased hand strength and dexterity.
- c. *Patient-related concerns:* The device should be easy and safe to use and present minimal harm to the patient if used both properly or improperly.
- d. *Competition:* Currently there is no commercially available device that fit these exact specifications. There are similar devices however they still require substantial hand strength for use. Further research will be necessary to determine whether the proposed design is a patentable idea.