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Lighted Ear Curette

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Lighted Ear Curette

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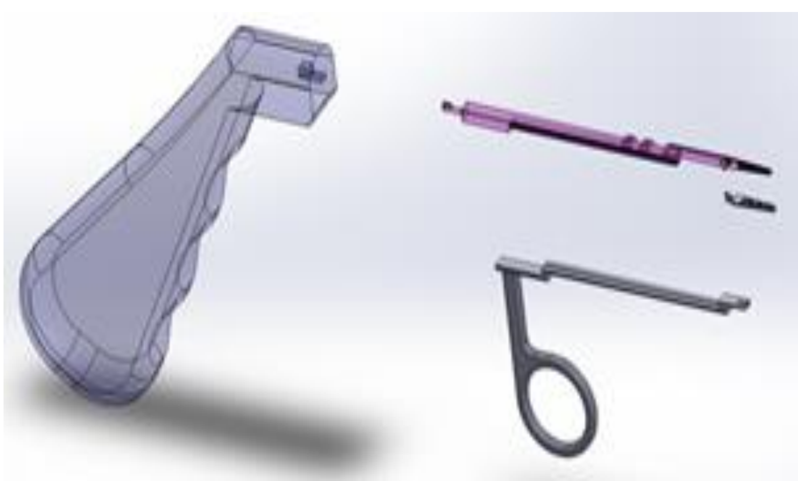

Abstract:

The ear canal is a sensitive and small part of the human body that is prone to accumulate cerumen or lodge foreign bodies. In order to clean the ear canal or remove foreign bodies, three hands are required: one to brace the patient's head, one to maneuver the curette that is used to clean the ear, and one to hold a light source in order to make the small, dark area visible. Therefore, a design is needed that can allow a doctor to safely clean an ear with an instrument that only requires two hands. Furthermore, the design must have disposable curette tip attachments in the form of both a scoop (used to clean the ear) and tweezers (used to remove foreign bodies), while remaining affordable.

To make this possible, a design was created that has both a tweezer and scoop disposable attachment that connect onto a reusable handle. A small lighted camera snaps onto the disposable curettes a few centimeters from the end of the tip. When the curette is inserted into the ear, the camera displays a video of the inner ear onto a screen, allowing the user complete visualization as they work, decreasing procedure time and increasing comfort.

This report outlines the background, design strategies and results of the ear curette design created. The resulting product is a prototype created using a 3D printer to demonstrate how the curette assembles and functions. Further development of this prototype and the creation of a complete manufacturing plan is necessary before it is ready to be used in a medical setting.

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Chapter 1: Introduction

1.1: Background:

Every day, medical doctors of varying specialties and practices see thousands of patients with all sorts of different problems, ailments, and injuries. In order to best help these people, many different medical devices have been designed to make their work easier, faster, more efficient and more effective. In this case, we were assigned to help out an emergency room medical doctor who came to the university with a specific problem he and his fellow doctors were having. The nature of this problem dealt specifically with the human ears. The ear drum and canal are not only sensitive and fragile, but also small. In this limited space, it is easy for small objects that get forced into the ear canal by some situation or another to become stuck and extremely painful to the person. The problem the MD was having was finding a device that was effective at removing both earwax and small objects. What he wanted was a design that is not only small and strong, but also flexible enough to keep from causing further pain to the patient and to have an ergonomic design that fit in the hand comfortably and could be easily manipulated.

In order to develop a product that fit all the doctor's needs and to be compatible with other models on the market, come at an affordable price, and be suitable for both hospital and home use, several criteria had to be met. Below is a list of all the things we wanted to work into the final design:

- Affordable
- Able to be sterilized with hospital procedures already in place
- Disposable tips
- Lighted mechanism

- Camera for visibility
    - Needs to be small to fit into the ear canal
    - Needs to be compatible with a monitor device
    - Needs to be easily mounted into design
- Light weight
- Ergonomically Optimized
- Stress Tested

1.2: Principles of Operation

Essentially, the way an ear curette works is that once it is determined that an object is stuck in the ear and won't come out on its own, action needs to be taken. The doctor will use a curette by first selecting the tip that will fit the scenario best (if an object needs grabbed, the tweezer tool will be utilized, if earwax needs removed, the scoop tool would be most effective, etc.). Then, if the curette has a light in its design, it will be turned on, and the doctor will then proceed to gently manipulate the object with the curette until it can be completely removed. Once the procedure has been successfully performed, the curette is then sterilized.

1.3: Product Definition

Short Design Brief:

The purpose of this project is to design an ear curette that is lightweight, durable, ergonomically sound, cost effective, user friendly, and FDA approved for a medical doctor. This process should be completed in the 24 week course of the Senior Design Class.

Expanded Design Brief:

The request to design an ear curette had a number of stipulations that needed addressed. For one, the product needs to be lightweight so it can be easily manipulated in the confined region of the ear canal. It also needs to be durable so that it will not shatter while in use, possibly adding to the problem at hand as well as holding up against hospital sterilization procedures. The curette also needs to be ergonomic, the doctor using the product for an extended period needs a comfortable design that won't irritate his or her hands. The cost of the entire system as well as the disposable tips needs to be high enough to cover the cost of the high quality materials but low enough to be affordable for the sake of disposable pieces. Lastly, the design should be FDA approved so that it can be used in hospital settings. The curette will be used by any range of doctors and other medical personnel to help alleviate the pain and problems of any number of patients in a range of scenarios. This process should be completed in the 24 week course of the Senior Design Class spanning from the beginning of the research to the end of the 3D modeling and manufacturing plan phase.

Chapter 2: Conceptual Design

With our product clearly defined (meaning our objective and constraints are clearly defined with background information and research collected), we created an overall function structure diagram for what we want our final product to include. An overall function diagram is illustrated in figure 1, while a more detailed one is shown in figure 2.

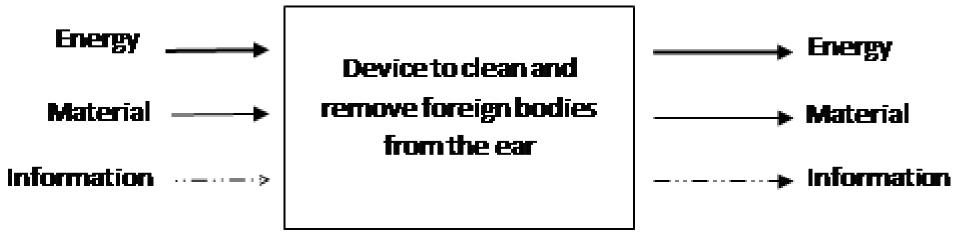


Figure 1: Function Structure Diagram

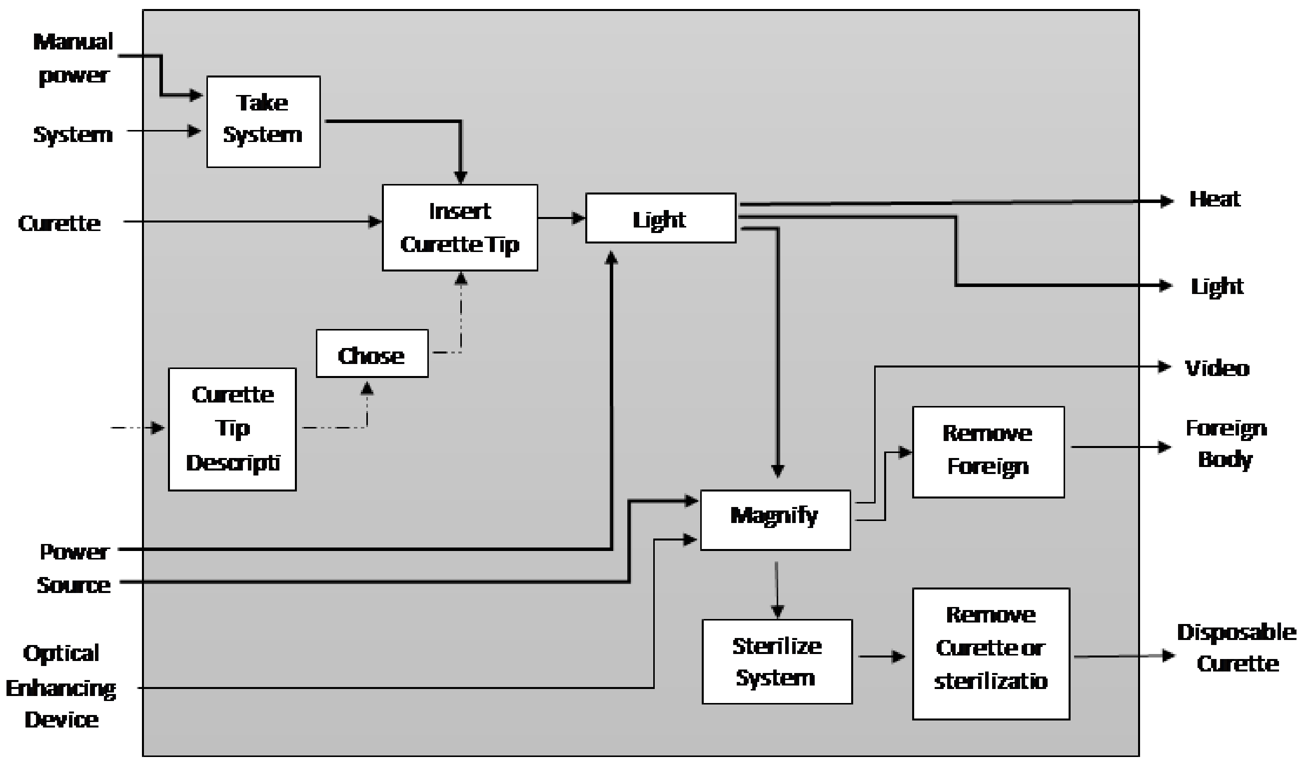


Figure 2: Expanded Function Structure Diagram

As demonstrated in figure 1, the desired function of our device is to clean and remove foreign bodies from an ear. The input elements going into the function are represented by the various lines in the figure. Figure 2 is an expanded, much more detailed diagram than figure 1 and gives further detail of the various function and elements necessary to reach our end goal.

Again, the lines between each function represent the elements of energy (thick, solid line), material (thin, solid line), and information (dotted line) that are required in order for each function to be made possible.

The function diagrams that we created include the various tasks that we want our ear curette to be able to achieve, including the ability to provide improved optics and lighting for the doctor. Exactly how those functions will be reached (for example, whether improved optics will be through a set of mirrors or the use of a camera), has yet to be determined, so the functions and how they will be reached are left as general terms in this point of our design.

In order to explore the many options that we have in order to achieve each necessary function, we created a morphological chart. If we are to fulfill all requirements and constraints, our final design has many variables to designed on top of just how our system will produce light and increasing. We also much chose the optimal material to maximize comfort, flexibility and strength while minimizing cost, define the necessary tip shapes and functions, determine a power source, include a safety constraint to prevent eardrum damage if possible, and define a manufacturing process. Each function, along with the design options, are illustrated in the morphological chart in figure 3.

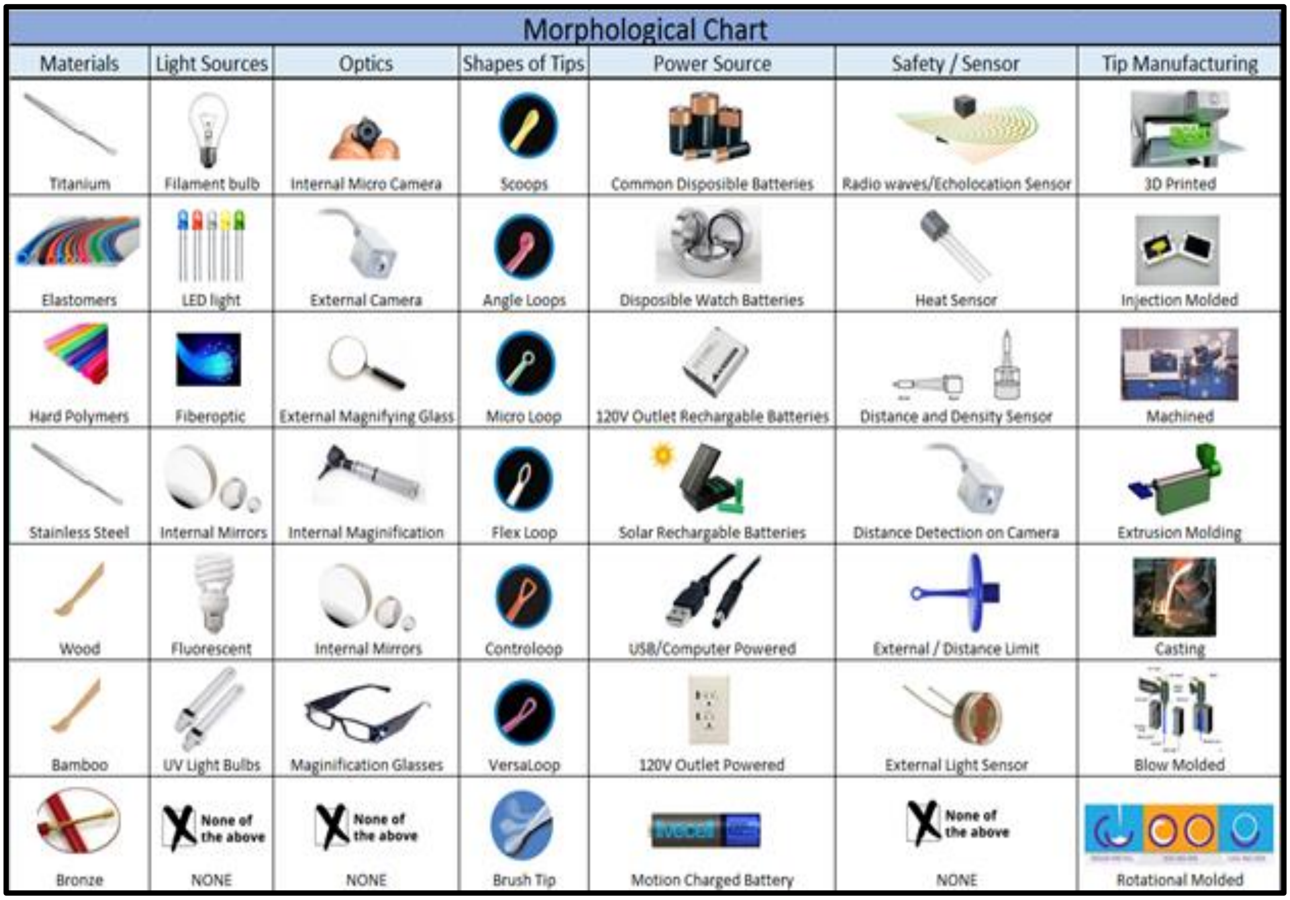
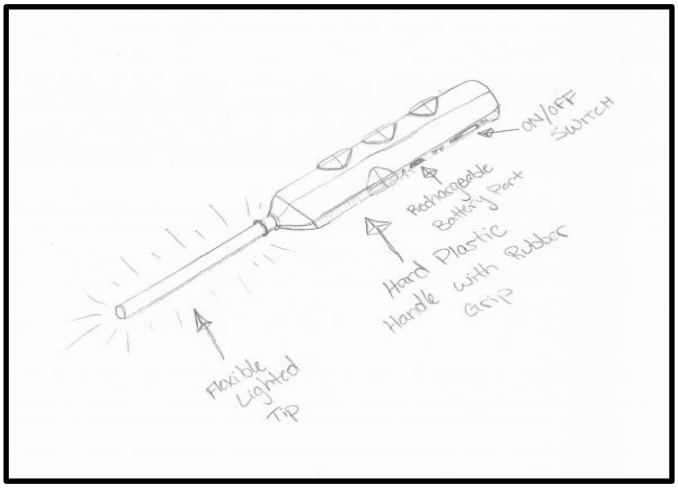
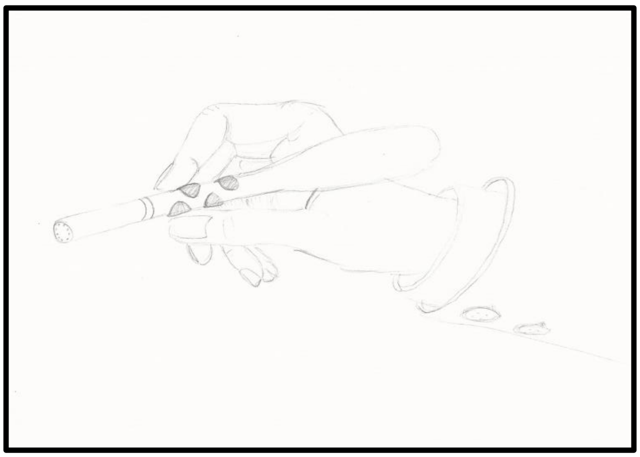


Figure 3: Morphological Chart

As evident in the morphological chart, there are many directions that we can take in creating our final design. Figures 4a-e are a few of our various concept sketches that we made while considering all of our option.





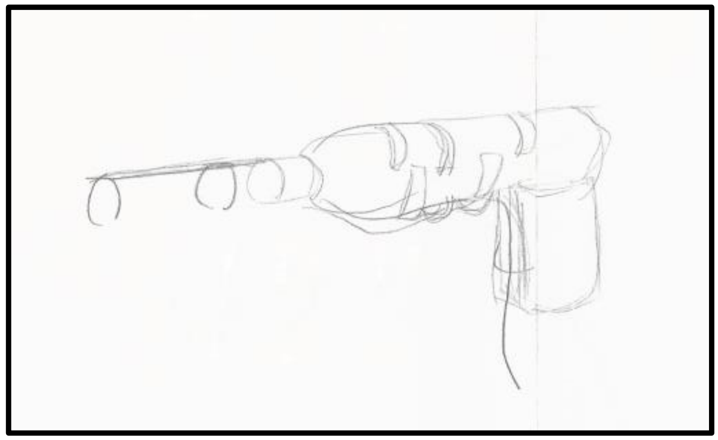
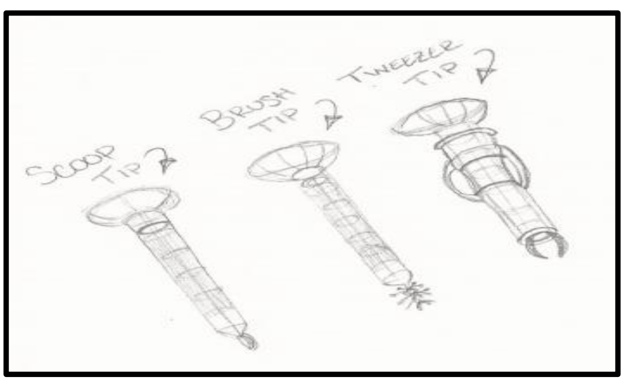


Figure 4a: Design concept sketch of a general design option



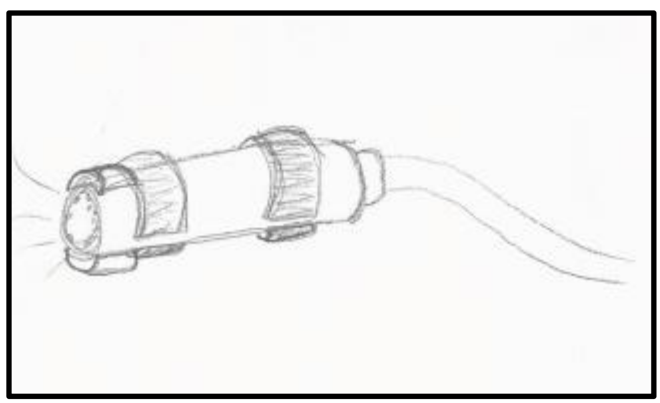


Figure 4b: Straight handle design option

Figure 4c: L-shaped handle design option

Figure 4d: Sketches of curette tip option Figure

Figure 4e: Lighted video camera design

In order to limit our options and determine the optimal design, we created an objective tree Figure 5 shows our final objective tree with each objective assigned a percentage based on its determined importance in the final design.

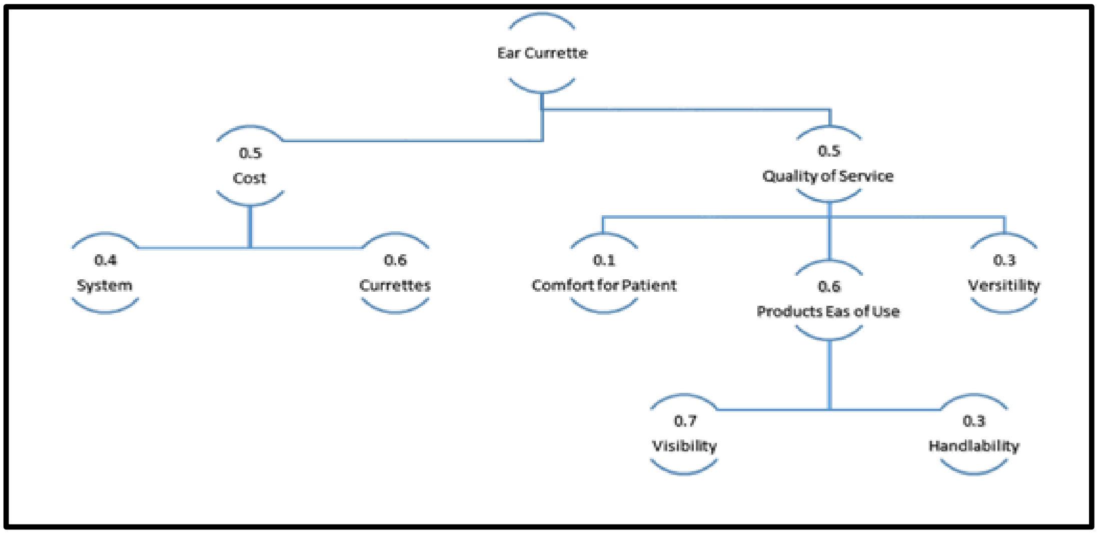


Figure 5: Objective Tree

The objective tree was then used to create a weighted decision matrix. The weighted decision matrix (Table 1), compiles five final design options. Each option has a variation of the desired functions of the final design. Although ideally, we will be able to produce an ear curette that is lighted, provides improved visibility through the use of a camera or set of mirrors, and has multiple disposable parts, all functions are not necessarily required in order to meet the customer's needs. Since limiting the cost is also a high priority of the project, it is possible that a function has to be sacrificed for the sake of price. The weighted decision matrix takes the importance of each objective (such as cost, comfort and visibility) into account along with how well each design option fulfills the objectives in order to give each option an overall rating. The design option with the highest rating is the design that will most sufficiently reach the objectives.

Table 1: Weighted Decision Matrix

Design Option		A		B		C		D		E	
		Unlighted		Lighted		Lighted with mirror		Lighted with camera		Lighted with camera and L-shaped handle	
Evaluation Criteria	Weight Factor	Score	Rating	Score	Rating	Score	Rating	Score	Rating	Rating	Score
System cost	0.2	10	2	9	1.8	8	1.6	6	1.2	6	1.2
Curette Cost	0.3	8	2.4	8	2.4	8	2.4	8	2.4	8	2.4
Visibility	0.21	2	0.42	4	0.84	6	1.26	9	1.89	9	1.89
Handle ability	0.09	7	0.63	6	0.54	7	0.63	8	0.72	10	0.9
Patient Comfort	0.05	5	0.25	6	0.3	7	0.35	8	0.4	9	0.45
Versatility	0.15	8	1.2	8	1.2	8	1.2	8	1.2	9	1.35
Overall Rating			6.90		7.08		7.44		7.81		8.19

Design options A through D each have a long, straight handle (much like in figure 4a and b), with the added functions described in their title. Design option E, on the other hand, has an L-shaped handle (as illustrated in figure 4c) to provide easy handling with a trigger-like mechanism that can be used to clamp a tong curette tip. In order to determine the score, each design option (A through E) were given a score from 0-10, 10 being the best and 0 the worst, for each evaluation criteria. This decision matrix is for the overall system. No matter the design of the system, we decided that each will use the same set of disposable curette tips with the material and shapes that we deem best. Initial design sketches for the curette tips are pictured in figure 4d. Therefore, each design is given a score of 8 for the cost of the curette. The remainder of the evaluation criteria were scored objectively based on their predicted ability to fulfil the criteria.

The rating for each criteria is found by multiplying the respective score by the weight factor. Finally, the overall rating is determined for each design option by adding the individual evaluation criteria. Design option E, “Lighted with camera and L-shaped handle”, has the highest rating and is therefore our final design.

Chapter 3: Embodiment Design

In the embodiment design the following seven components were designed; the handle, top forceps, bottom forceps, pin, trigger, scoop and lighted camera. In figure 6 this shows the first rough hand sketch of these components.

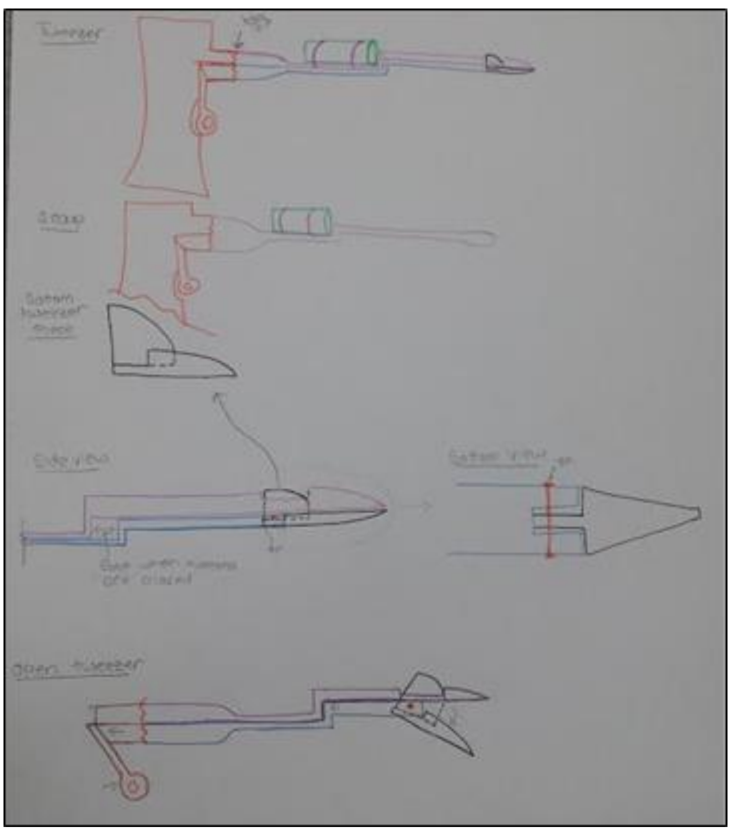


Figure 6: Schematic diagram of embodiment design

For the ear curette, the decision was to go with two attachments. These two component attachments are called the scoop and tweezers. The top forceps, bottom forceps, pin and trigger are the components to the assembly of the tweezers. The scoop is just one piece that does not require assembly. These attachments are disposable after each use and easily attached and removed. The connections between the handle component and the disposable attachments are shown in figure 7.

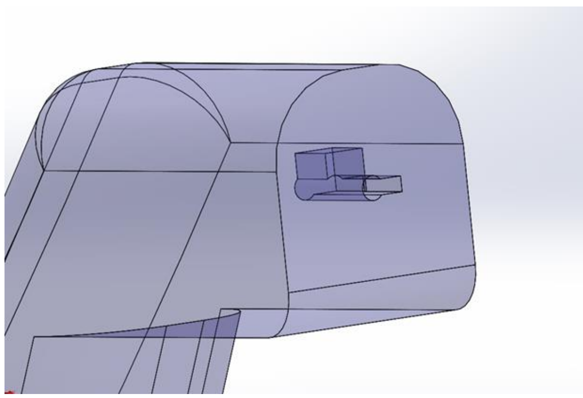


Figure 7: Connection between attachments and handle

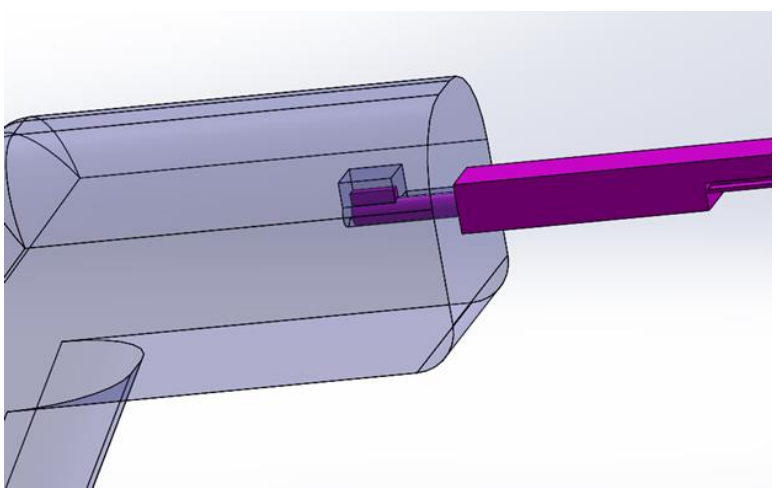


Figure 8: Connection of attachment and handle

As shown in figure 7 and 8, there is a cut out in the handle that allows the mating piece from the disposal attachments to slide in then turn 90° to lock in place. The connection for the top forceps and the trigger is a slide that allows the bottom forceps to open and shut. The bottom forceps component has two pins. One pin is locked and the other allows for rotation therefore allowing it to actuate as the trigger slides back and forth. This connection of the bottom forceps and trigger can be found in figure 9.

Figure 9: Exploded view of tweezer attachment

Figure 10 shows the camera used for the embodiment design. This camera is USB enabled with an integrated LED light source. As shown in figure 11, a step and camera clips were designed to accommodate for the size of the camera used. The camera diameter is 5 millimeters therefore, the step on the attachments allow enough clearance for the camera to enter the ear with the tweezers or scoop. This camera is also easy to clean using any hospital approved solution and can be reused.

Figure 10: LED Lighted Camera

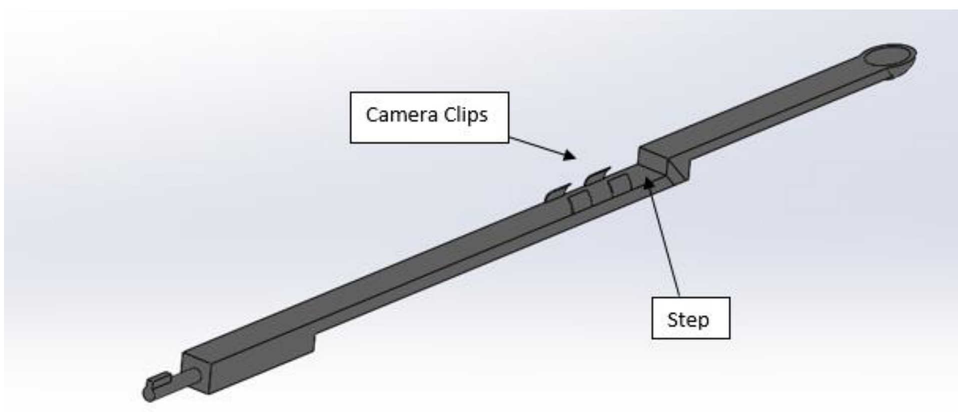


Figure 11: Attachments with step and camera clips

The material which was selected for all of the components was PVC or Polyvinylchloride. Although this material is not yet FDA approved, it is used in various applications in the medical field. This material is desirable due to its chemical stability, biocompatibility, flexibility, durability, dependability, ability to be sterilized, lightweight and low cost. Chemical stability and stabilization are important to consider when designing for medical devices since hospitals and other possible consumers will be cleaning the non-disposable components. The nonporous surface of PVC can be easily cleaned after each use with a chemical solution or soap and warm or hot water. The material should also be able to withstand more rigorous cleaning methods including harsher chemical solutions, yet labels should be displayed to discourage customers from using steam Autoclave or other similar devices are used for sterilization since the temperature rises over 121˚C (250˚F) and the melting point is 90˚C (194˚F). The flexibility of PVC was desirable to reach into deeper areas of the ear canal and scrape away any foreign bodies or cerumen without hurting the patient. A material's durability and dependability is always important to ensure the system does not break and become lodged in a patient. The low cost and easy manufacturability of the material allows us to have disposable components to provide an extra measure of sterilization which can be recycled.

The cost of PVC as of April 24, 2017, the price of suspension resin injection GP was between $0.81 to $0.86 per pound. According to the Alberta Occupational Health and Safety laws or OHS laws, a small precision hand tool should weigh between 0.9 to 1.75 kg (about 2-4 lbs.). Therefore, using the maximum weight and price, each unit should be less than $3.50 for material costs. Manufacturing costs would be dependent on the method used, for example, 3D printing could cost more or less than injection molding. The disposable components could be sold in sets for $4.00 to $5.00, the number of attachments per set will be determined after manufacturing and material costs are calculated and will also be dependent on which of the attachments is being purchased. The cost of the endoscope camera with USB connection that was used for the prototype was less than $15. There are also other micro cameras with lighting and Bluetooth options which can cost up to $1,200 or more. Designs could be made to the model if other camera options are desired. The total cost of the device and camera would be around $20 or more for materials only.

Chapter 4: Detailed Design

The final Ear Curette design consists of four components: a Handle, a disposable scoop attachment, a disposable tweezer attachment, and a detachable lighted camera. 3D models created in Solidworks of the handle and trigger components are shown in figures 12-13, while the camera and scoop are illustrated previously in figures 10 and 11.

Figure 12: Model of Handle

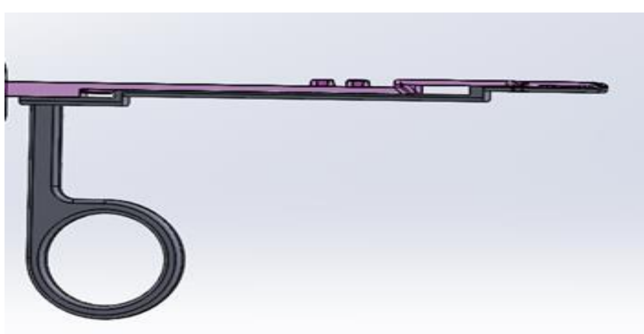


Figure 13: Model of Disposable Tweezer Attachment

The handle is designed for the comfort of the average human hand. The decreasing diameter, built in grips, and angled design allow the user the room and grip necessary to comfortably and accurately handle the tool.

The two disposable curettes are included in the design and both can be connected to the handle by inserting them sideways, then turning the tip counterclockwise to engage the locking mechanism that secures it in place. Both have clips on the top surface where the camera can be snapped into place. In order for the curette to be thin enough to fit inside of the ear (exact dimensions are discussed later), the tip raises to half the height of the camera right beyond where the camera attaches, then extends out. This allows for the camera to fit just inside the ear to provide visibility of the canal, while the tip can extend further to reach the desired area. Both tips are meant to be disposable after each use in order to abide by all FCA regulations and keep the design safe and sanitary.

The tweezer attachment consists of four components: an upper and lower curette, a bottom tweezer and a pin. The individual components of the tweezer are pictured in figures 14-17, while the assembled view is shown previously in figure 13. The lower curette consists of a trigger and has a groove that coincides with the upper curette, allowing the two to be attached by easily sliding them together. The end of the tweezer fits into a hole in the upper curette, and a pin is used to secure it to the lower curette. The lower curette has a trigger that the user pulls to close the tweezers, and pushes to open them again. This tweezer attachment was modeled after the alligator forceps provided to us by the doctor and pictured in Figure 18.

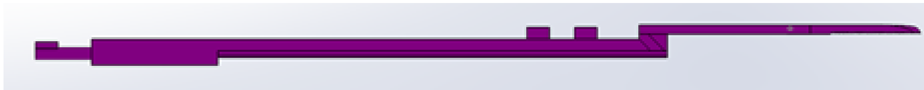


Figure 14: Upper component of tweezer curette

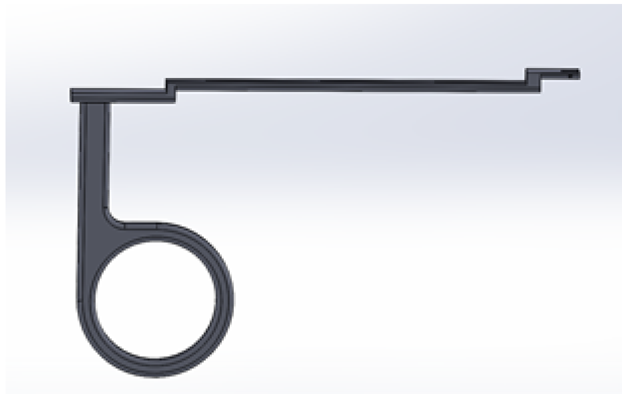


Figure 15: Lower component of tweezer curette

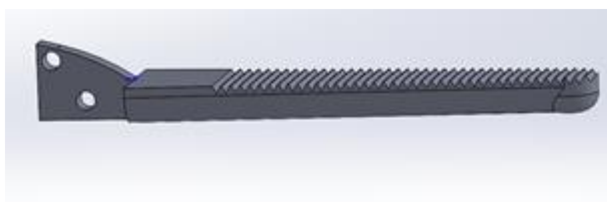


Figure 16: Bottom tweezer

Figure 17: Pin

Figure 18: Alligator forceps

Finally, the camera, pictured in figure 10, is 5mm in diameter. It has built in LED lighting and can be connected to a computer with a USB cord. The computer acts as a power source as well as a display for the image that the camera views.

Figures 19 models the entire curette fully assembled with the tweezer attachment, while figure 20 is an exploded assembly view. The figures do not include the camera, which will attach to the clips on top of the tweezer curette.

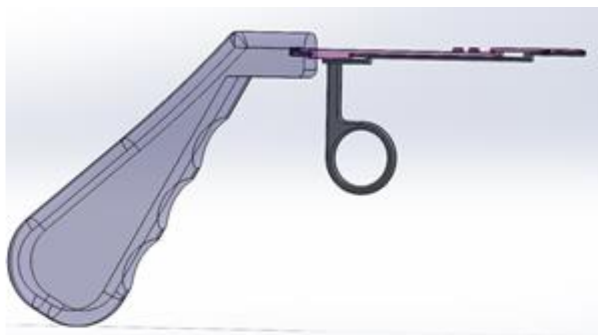


Figure 19: Full assembly with tweezers

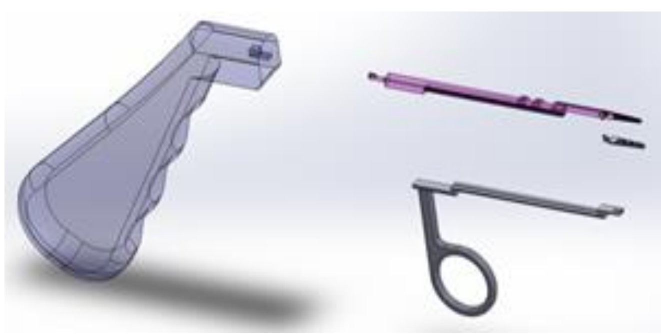


Figure 20: Exploded view

In order to fit inside of an ear canal to reach the desired location, both tips need to be fairly thin. Figure 21 is a diagram of an ear canal with the average dimensions. Dimensions can vary significantly based on gender and age. For the purpose of this design we chose to design for the average adult ear, with a canal length of 30 mm and diameter of 6mm. Since the camera used is 5mm in diameter, a practical design was not possible that consisted of the camera in the very tip of the curette, which is why our design has the lift directly beyond the camera attachment location. Since the distance from the inner ear (where the camera can reach) to the eardrum (the furthest the tool would need to reach) is so minimal (about 3 cm), having the camera set back from the tip will still provide the necessary visibility for the user.

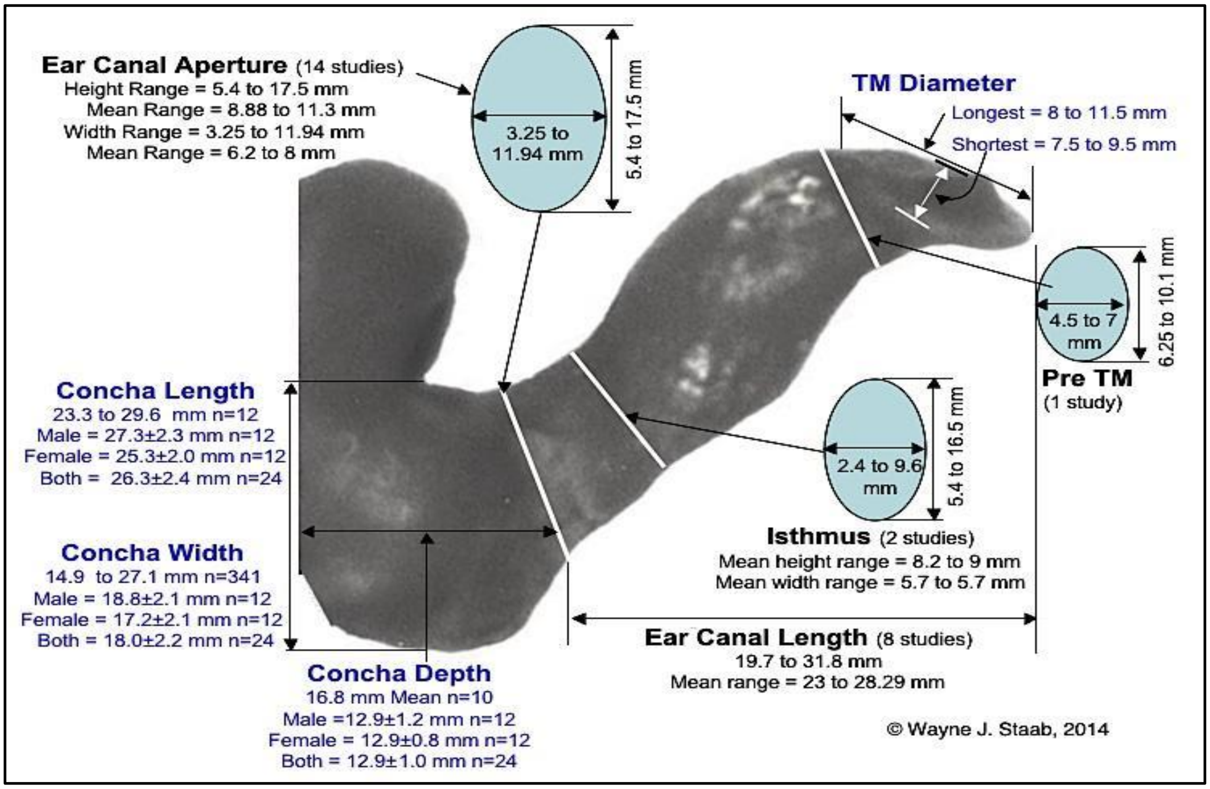


Figure 21: Average ear canal dimensions

Based on these constraints, the final design consists of tips 15.25 cm in length and the tips are about 2.2 mm thick. The distance from the end of the camera to the tip of the disposable curettes is 4.75 cm.

Before we printed out our model we needed to run a stress analysis to make sure that the design was going to work and not break. We used the stress analysis feature in SolidWorks to help us determine if our model was going to hold up to the stresses and strains of normal use. Figure 22 shows the stress analysis we did on the trigger portion to make sure that the trigger would not break off during use. As you can see from figure the trigger is not going to break off. Our design for the trigger is good to move onto the printing step.

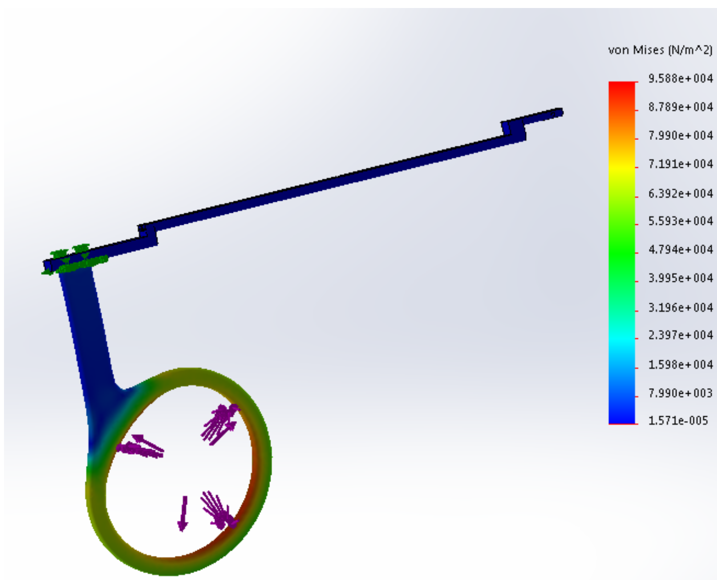


Figure 22: Stress analysis for trigger

Next we had to check the scoop to make sure it would hold up to the stresses and strains. As you can see in figure 23 the trigger is not in the red zone so our scoop will hold up under the stresses of being used. Now that we know our entire model will hold up under the stresses of being used we can move on to the next phase of the project, and send the model to be 3D printed.

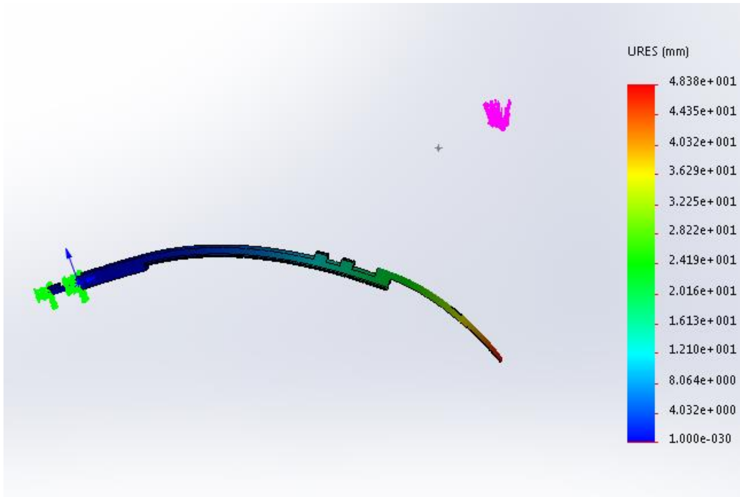


Figure 23: stress analysis for scoop

The design created is meant to be a prototype, and further testing, improvements and planning are necessary before it can be manufactured for regular use. Therefore, an exact manufacturing plan is not yet in place for our product. The prototype was created out PLA material using a Microbot 3D printer. Figure 24 is a photo of the final 3D printed prototype including the handle and both curette attachments (the scoop is on top, while the tweezer assembly is below). Figure 25 demonstrates the prototype with the scoop and camera attached, while figure 26 demonstrates the use of the prototype on a model of an ear canal.

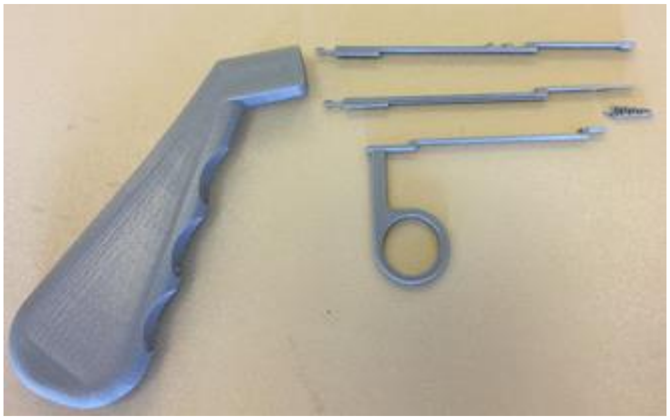


Figure 24: 3D printed model

Figure 25: 3D printed model with scoop attachment and camera

Figure 26: Prototype demonstration on an ear canal model

Once printed, the design could be further analyzed to where design flaws and possible improvements could be determined. Suggestions for future improvements are discussed in Chapter 6: Recommendations, following.

As previously mentioned, the design produced is a prototype and still requires further development before it can be finalized and a manufacturing plan can be made. Therefore, we do not have a price estimate for the ear curette design. However, we did create a BOM for an Ear Curette package consisting of ten replacement scoop and tweezer curette tips, shown in Figure 27. Since the curette tips are disposable, final packages will consist of multiple tip attachments, while only including one reusable handle and camera. To limit cost, replacement disposable curette tips will also be available to be purchased separately from the handle and camera. For the sake of demonstration, just the 10 pack is illustrated.

Assembly Number	17-001					
Assembly Name:	Ear Curette-10 pack					
Assembly Revision:	A					
BOM Level	**Part Number**	**Part Name**	**Quantity**	**Unit of Measure**	**Phase**	**BOM Notes**
1	17-101	Handle	1	Each	In Design	Base Product only, No packaging
2	17-211	Scoop Curette Tip	10	Each	In Design	10 Pack Quantity
2	17-221	Upper Tweezer Curette Tip	10	Each	In Design	10 Pack Quantity
2	17-222	Lower Tweezer Curette Tip	10	Each	In Design	10 Pack Quantity
2	17-223	Tweezer Tip	10	Each	In Design	10 Pack Quantity
2	17-224	Pin	1	Each	In Design	10 Pack Quantity
3	17-301	Camera	1	Each	Outsource	

Figure 27: Build of Material of an Ear Curette 10 Pack

Chapter 5: Discussion

A number of milestones in the design phase were met to achieve the prototype printed for the sake of aesthetics. For one, a large amount of research has been conducted and through this, a vast range of products have been referenced, materials have been evaluated, and processes analyzed. Not only this, but the budget has been addressed and we have met with the doctor and interviewed him as to what he expects and his feedback on our progress. The doctor then provided the group with a sample curette that he was currently using that wasn't up to his standards, but gave us an idea of what he was working with. Using this example device, we were then able to model our product with those features included, as well as a few improvements and enhancements to create a superior model incorporating the most valuable features of a number of existing products into one functional design.

Once all of the required features were included in our model, it was possible to utilize SolidWorks to create our final product in 3D and have each individual piece printed out on a 3D printer. With the 3D software, it was possible to also perform a number of stress analysis tests to determine if the selected material would hold up against the usual functions that the medical doctor would use the product for. Not only did the selected material hold up, but it exceeded the requirements in all of the weakest points, including the connection points, the trigger, and the pinch jaws at the far end of the model.

The selected material of PVC is an optimal choice for several reasons. For one, it is cost efficient, making it an enticing choice for any medical device buyer and supplier. For another, it is a durable material that holds up against the sterilization processes of a hospital, for years PVC has been repeatedly selected for medical device production and has withstood the test of time and proven its reliability. Also, if the situation calls for a stronger material, the software makes it remarkably simple to run tests on the model and determine if it will hold up against the same stresses or impose new forces and see its reaction and determine its validity before production. This new design has a number of features and qualities that surpass the competition. The price after initial capital costs are absorbed will be very affordable for any range of consumers from commercial hospitals to office visits to home use. The lightweight design that features disposable tips, a small USB enabled camera, and a strong handle/trigger function sets this design as an industry success before it even hits the market. The only drawbacks that the model might have would be the cord that enables the camera to show a live video of the device progression inside the ear canal and perhaps the size constraints of a child's ear. Both of these drawbacks could be easily alleviated with a scale down depending on the dimensions of a child's ear canal and a Bluetooth enabled camera. The camera would then require a rechargeable battery port on the handle and possibly a charging stand/station. These changes would require some added initial costs and the camera would result in a higher price per unit but the benefits would outweigh the costs in the long run.

Chapter 6: Recommendations

This project has a number of facets yet to be explored in order for the product to be a market leader and the most valuable option for medical doctors. For one, the device should be scaled back for the use of a doctor in procedures involving children. Due to the size constraints of a smaller human, the dimensions of the device could be reduced to retain all functions but be optimized for a whole new range of patients. In addition, the design could be made to include a smaller camera. The existing camera is larger than what would be best and if the camera had a Bluetooth with rechargeable battery option instead of a bulky cord the product would be much more valuable to the consumers. If a camera with a cord is used, modifications to the handle could be made to keep the cord contained. Also, the current design has the camera attached to the top of the curette because of the large size, if a smaller camera is discovered, restructuring the device to have the camera inside the design would probably facilitate the sterilization process. Decreasing the length and adding a slight curvature to the end of the attachments could be beneficial to allow the user to see exactly where the tip located and have better control to decrease the likelihood of puncturing the eardrum.

Another aspect that could be explored would be another material, although PVC seems like the best option, medical advances are always being made and a better polymer combination is sure to come to the surface soon and, if it holds the correct qualities, could prove to be a more advanced option.

As a designer, we should also try to foresee other applications where the design could be used. Other design factors would need to be examined if other uses are imminent. As an example, a medical professional may decide to use this device to remove an object from a patient's nose, this introduces different angles of force being used and could require greater clamping force to remove larger objects.

Finally, a mass manufacturing plan including the production source, process, and packaging options need to be explored. This final step, along with quality testing at 3rd party labs to ensure medical device approval would wrap up the project and send it on its way to market for a long lasting career in easing the work of medical doctors all over the globe.

Chapter 7: Conclusion

After consulting with a medical doctor, the team has designed a new device to clean and remove foreign bodies from the ear. In the first semester of this course the background research and conceptual design stage was completed. The background research included the study of existing products in the market and implementation of features we want to incorporate into the design. During the conceptual design stage a function structure diagram, morphological chart, concept sketches, objective tree, and a weighted design matrix was created. From the weighted design matrix design option E, “Lighted with camera and L-shaped handle”, had the highest rating. With this information, the team performed the embodiment design stage, as well as the detailed design stage, and were able to model the prototype with 3D modeling software. With this phase complete, stress analysis was performed, ensuring the sustainability of the material with the required design. With the test results showing a passing level of strength and functionality, the model was 3D printed.

Once the device was printed and each piece was analyzed, even in its scaled up state for inspection purposes, the model seems to validate the functions the team set out to accomplish. From this point, it was determined that the way to proceed from this point would be to implement the development of some different options including a Bluetooth camera and a device optimized for children. Both of these options as well as a plan for mass production are very attainable with the progress that has been made thus far.

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