

Silicone Oil Applicator for Medical Devices

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Abstract

Currently, Rusch Silkospray is used at the UW-Hospital in Madison, WI to lubricate various medical devices such as bronchoscopes, single lumen endotracheal tubes, and catheters before they are used in the operating room. The current spray, however, is not ideal because it can create slippery work environments, its particles can be inhaled, and it can cause cryogenic burns (i.e. frostbite). A disposable pad, clamp, and enclosed box design were created to solve these issues. After evaluating each design, the enclosed box was chosen as the final design, and three prototypes were constructed. Testing was conducted on the second prototype, which found that the enclosed box design eliminates the overspray created by the Rusch Silkospray. Future work for this design includes making and testing a fourth prototype.

1.0 Introduction

1.1 Problem Statement

The clients, Dr. Richard Galgon and Dr. George Arndt of the UW-Madison School of Medicine and Public Health, Department of Anesthesiology, work as anesthesiologists at the UW-Hospital. Currently, surgeons and doctors (e.g. anesthesiologists, pulmonologists, critical care medicine physicians, and emergency room physicians) use Rusch Silkospray, an aerosolized medical grade silicone oil, to lubricate upper airway tubes, catheters, and bronchoscopes in the operating room, pulmonary suite, intensive care unit, and emergency room. The tubes and devices need to be inserted inside a tube that is placed within the patient's upper airway as shown in Figure 1. The lubricant is applied to the outside and inside of medical device, which allows them to slide past one another with ease. This prevents anesthesiologists from having to continuously remove and replace the tube within the patient or forcefully jam the inner device through the tube, both of which could injure the patient. The devices include, but are not limited to: fiberoptic bronchoscopes, single and double lumen endotracheal tubes, airway exchange catheters, Aintree intubation catheters, bronchoscopes, laryngeal mask airways and other supraglottic airway devices, airway circuit adapters, and bronchial blockers. Although the aerosolized silicone oil sufficiently lubricates these medical devices, the current application technique poses three main problems: (1) creates a slippery work environment presenting a risk of injury to personnel and patients, (2) poses a risk for cryogenic burns (i.e. frostbite), and (3) releases particles into the air that can be inhaled. A different effective method of applying the silicone oil to these devices that eliminate these problems is sought.

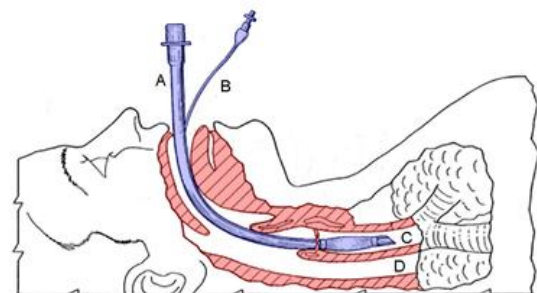


Figure 1. Endotracheal tube placement within patient that would have other devices inserted within it. The lubricant allows the devices to slide past one another with ease so as not to hurt the patient.

1.2 Background

1.2.1 Background of Silicone Oil

Silicone oil is waterproof grease produced by mixing polydimethylsiloxane with a thickener, such as amorphous fumed silica. Silicone oil is thermally stable, fire resistant, and resists incorporation of air bubbles into the liquid. Silicone oil is manufactured in different

purities including a food grade and a medical grade. It is available in both a liquid and an aerosolized form, as shown in Figure 2. It is used in electrical applications requiring a lubricant as an insulator. Silicone oil is also used widely in the medical, automotive, and manufacturing industries as a lubricant to devices and machinery (Silicone and Silicon, 2006). This design is focusing on silicone oil's application as a lubricant for medical devices.

1.2.2 Aerosolized Silicone Oil Lubricant Safety

In viewing the material safety data sheet for several aerosolized silicone lubricants, it was determined that silicone oil is relatively safe if used correctly. Aerosolized silicone oil is under high pressure and uses propane and butane as propellants (LPS, 2011). These aerosol propellants make the canister of silicone oil flammable. A potentially dangerous situation when using aerosolized silicone oil can be avoided by keeping flames and heat sources away from the product (Dupont, 2011).

It is recommended that users of aerosolized silicone oil equip themselves with respiratory equipment, safety goggles, and protective gloves when coming into prolonged contact or repeated exposure to the spray (Betco, 2007). Contact with the eyes will result in irritation, and repeated exposure of the skin to the silicone oil can result in dryness and cracking (IMS, 2011).

1. 2.3 Cryogenic Burns

Although silicone oil itself cannot cause cryogenic burns, propane and butane, which are used as propellants in the aerosol, can. Butane has a boiling point of -5°C , and propane has a boiling point of -41°C (Sigma Aldrich, 2009). Because both propellants have low boiling points, when the pressurized propellants are released, they quickly vaporize and absorb heat from the surrounding environment. The sub-freezing environment created by these propellants can damage skin tissues and cause cryogenic burns (Aerosol-Induced Frostbite Injury, 2011).

There have been a few documented cases of cryogenic burns caused by aerosol propellants. In Switzerland, there was a 14 year old girl who developed first degree cryogenic burns after she used a deodorant spray containing propane and butane propellants (Aerosol-Induced Frostbite Injury, 2011). There have also been other children that received cryogenic burns after using aerosolized products containing propane and butane as propellants, such as toilet air fresheners (Camp, 2003 and Lacour, 1991). In all cases, the user of the aerosol had misused the product and sprayed for extended periods of time. Various factors can contribute to the severity of the cryogenic burn. The ratio of propellant to solvents, the heat of vaporization of liquid, and size of the droplets can all possibly affect the severity of the burn (Moser, 1999).

1.2.4 Particle Inhalation and Irritation

The aerosolized silicone oil can be easily inhaled because it suspends its particles in the air. Prolonged exposure and use of aerosolized silicone oils have been linked to respiratory problems (Conrad, 1994). Excessive inhalation can lead to irritation of the respiratory tract, nausea, dizziness, or headache. The use of such aerosols in operating rooms is currently under scrutiny by the Occupational Safety and Health Administration (OSHA). They want to impose



Figure 2. Silik'On silicone oil lubricant.

stricter standards on the necessity of wearing the proper respiratory masks to protect surgeons from inhaling silicone oil particles along with other inhalants in operating rooms (LPS, 2011).

Propane and butane within aerosolized silicone sprays have also been documented as a source of mucous membrane irritation when the spray was used as a lubricant for endoscopy procedures. Although the silicone oil was not the cause of the irritation, the aerosol contains butane as its propellant, so this issue is something that must be kept in mind when performing endoscopic procedures with aerosolized silicone oil (Rusch Silkospray, 2011).

1.2.5 Slippery Surfaces and Floor Hazards

Aerosolized silicone oil can create slippery surfaces, which can cause problems on the floor of workplaces. A slipping hazard is created for any workers in the vicinity when the floor is covered with silicone oil (Valencia, 2006).

2.0 Motivation

The main concerns with the current aerosolized silicone oil are that it can create a slippery environment, has the potential to cause cryogenic burns, and emits particles that can be inhaled. To coat the inside of medical devices, doctors spray the silicone oil into the packaging of the device. To coat the outside of the medical devices, doctors hold the device over a trashcan while spraying in an attempt to contain the spray. Even with these techniques, a slippery environment occurs and particles are inhaled. For these reasons, other hospitals have banned the use of aerosolized silicone oil from the operating room. Lubrication is essential to a successful operation; therefore, it is necessary to resolve the problems caused by the aerosol spray.

3.0 Design Specifications

3.1 Client Requirements

The alternate method of applying the silicone oil must adhere to the requirements set forth by the clients. Most importantly, the device must use the existing Rusch Silkospray aerosolized silicone oil. The device must prevent the spray particles from being released into the air where they can be inhaled. The device must not allow the spray particles to settle on workplace surfaces, such as the floor. A way to protect the user from the cold effects of the propellants in the aerosol spray is also needed. The device should be able to coat the inside and outside of medical tubes and devices within 30 s. The device must be able to coat both the inside and outside of the listed medical equipment with internal diameters ranging from 2.5 mm to 9 mm and external diameters up to 13.7 mm. The longest length of medical equipment that would need to be coated is 35 cm long. The device should be portable and less than 10 cm X 10 cm X 10 cm. To avoid complicated cleaning processes, the device needs to be disposable and mass producible so that it can be replaced for each patient. The overall production of the device must be less than \$1000.

3.2 Ethics

As with any engineering design, the topic of ethics must be considered while designing the device. The design of the device must not pose any ethical issues. In order to ensure this, the device must be made from materials that are safe for humans. In addition, the device must not hinder the ability of the surgeons to perform their job. Also, the device must pose no risk of cross contamination between patients or cause adverse health effects. The design aims to eliminate the particles of spray that can be inhaled and the slipping hazards within the operating room. This

will save the personnel pain, money, and time that may otherwise have been invested in healing the employee from an injury.

3.3 Ergonomics

As the design will be used in the limited space of the operating room, it must take up a maximum space of 10 cm X 10 cm X 10 cm. Furthermore, the prototype must be user friendly and easy to intuitively use. Because the silicone oil sometimes needs to be applied in a limited time frame, the device should be able to be assembled in less than 10 s, and the lubricant should be able to be applied in 30 s or less.

4.0 Existing Devices

There are several common types of existing devices that are used to apply silicone oil. There is a bottle brush applicator, a syringe applicator, and an automatic silicone oil applicator machine.

4.1 Brush Applicator

The advantage of a brush applicator, as shown in Figure 3, is that it is readily available and only \$4.00 per brush making it relatively cheap (Tool Shack, 2011). This product is able to coat the outside of medical devices; however, it cannot adequately coat the inside of small tubes. This will not work for the application of the lubricant to both the inside and the outside of medical devices.



Figure 3. Brush applicator for silicone oil lubricant (Tool Shack, 2011).

4.2 Syringe Lubricant Applicator

Another existing applicator is the syringe tool, shown in Figure 4 that uses liquid silicone oil (High Island Health, 2011). The syringe works well for lubricating the inside of devices; however, it cannot lubricate the outside of medical devices. The small amount of lubricant that the syringe can dispense at once is not enough to coat the inside or the outside of the medical devices in the timely manner that is required for an operating room. Also, the syringe does not use the aerosol form of the silicone oil that is currently available at the UW-Hospital.



Figure 4. Syringe Lubricant Applicator (High Island Health, 2011).

4.3 Automatic Silicone Oil Spray Chamber

McClellan Automation makes the automatic silicone oil spray chamber shown in Figure 5. This chamber is specifically designed for coating medical devices (McClellan Automation Systems, 2006). Although, the chamber eliminates the need for a person to apply the silicone oil directly, thus eliminating the hazards mentioned previously, the chamber is costly and cannot be used in an emergency situation.



Figure 5. Automatic silicone oil spray chamber (McClellan Automation Systems, 2011).

5.0 Design Proposal Overview

5.1 Design 1: Disposable Pads

The basis of the first design is to transform the aerosolized spray into disposable pads soaked in silicone oil. To accomplish this, an initial prototype of a cylindrical canister with a height of 8 cm and a diameter of 7 cm containing disposable cotton pads would be attached to the nozzle of the Rusch Silkospray bottle via a tube as shown in Figure 6. When the nozzle is depressed, the tube would direct the spray into the canister, thereby soaking the cotton pads in silicone oil. The canister would contain a removable lid similar in design to a coffee canister lid, which would ensure that the oil does not leak into the surrounding environment when the pads are being sprayed. The canister would contain a gasket on its side that would close once the canister is removed from the can. This ensures that the cotton pads would remain soaked with the oil and not dry out. The canister could then be brought into the operating room instead of the aerosol can.

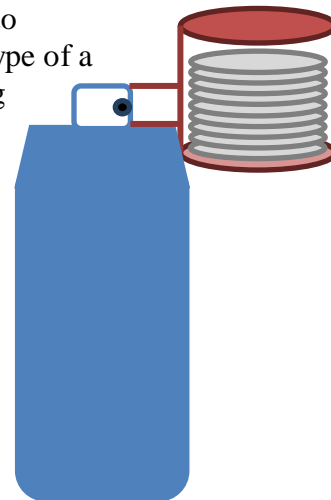


Figure 6. Disposable pad design

To coat the outside of the various medical devices, the user would remove the lid and rub the cotton pad over the outside of the device. To coat the inside of the medical tubes, the fibers of the cotton pad would be looped into a hook attached to the metal rod shown in Figure 7. The rod would be 42 cm long, which would ensure that it would fit through the longest tube used by the client. It would be made of metal material that would allow it fit through the curves of the tube without getting stuck or caught. This risk getting caught would further be decreased by having a loop at the opposite end of the hook. The user would string the wire through the tube and pull the wire through, which would cause the silicone oil soaked pad to be pulled through as well, thereby coating the inside of the tube.



Figure 7. Rod to coat the inside of tubes

There are several advantages to this design. The canister would contain the spray, so the spray would not be able to leak into the operating room, thus decreasing the slippery environment that the current method creates. Also, because user is not spraying directly into his/her hand, the hazards due to the cold environment created by the propellants would no longer be an issue. This design is relatively small, so it would occupy minimal space in the operating room and remove the need to bring the can into the operating room entirely.

Although the design does resolve the three main problems with the current method, there are several flaws associated with it. Because the user uses his/her hands to run the cotton pad on the outside of the tube, this may cause his/her hand to be coated with silicone oil as well. The smallest diameter of the tubes is 2.5 mm, so the cotton pad may be too big to pull through the inside of the tubes to coat them with the oil. Because the canister is closed when spraying the pad, a buildup of pressure in the can due to the propellants in the aerosol may occur. Also, this design has few outside applications; therefore, it is not very marketable, which would hinder its chance of mass production. Yet another issue is the risk of cross contamination. When removing a pad from the top of the canister, the user may contaminate the other pads; therefore, each canister could only be used for one patient.

5.2 Design 2: Clamp

The second design option is the clamp design, which is shown in Figure 8. It would attach directly to the top of the silicone spray can and would be held in place by a strap that wraps around the bottom of the can. For this design, the nozzle would have to be reengineered so that it sprays the lubricant vertically instead of horizontally. The nozzle of the aerosol would rest in a series of notched holes shown in Figure 9, which enable the lubricant to be released by pressing down on the clamp. In accordance with the design specifications, there are two main facets to this design: the mechanism to coat the outside of tubes with lubricant, and the mechanism to coat the inside of tubes

The clamp design works well in its ability to coat the outside of tubes with silicone oil. In order to do this, the user would close the clamp and apply a downward force on it. This force would depress the nozzle and cause the silicone oil to spray inside of the clamp. The inside of the clamp features two sponges, one on each surface. Spraying the lubricant would cause the sponges to become saturated with silicone oil. A medical device, such as an endoscope, that requires lubrication on its outer surface could then be inserted into the clamp and ran

through it. The sponges would adequately coat the device's outer surface with silicone oil.

In order to cover the inside of tubes, a different mechanism would be used. The user would first remove a stopper from the top of the clamp, which would expose a hole that ran through the entire clamp to the nozzle of the aerosol can (see Figure 10). The user would place the tube on top of the clamp such that it completely covered the mouth of the hole. The user would then close the clamp and press down on it allowing the spray be dispensed vertically. The spray would run through the entire clamp, emit from the top, and flow into the tube. Via this mechanism, the user could successfully coat the inside of tubes.

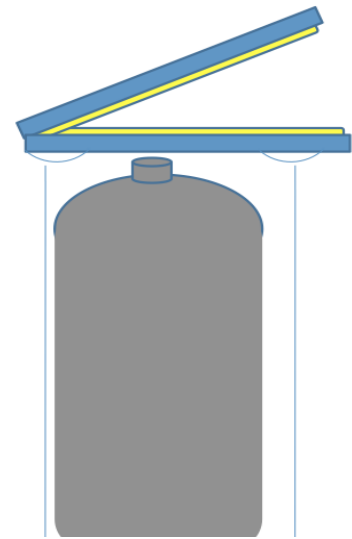


Figure 8. The clamp design mounted to the top of the aerosol spray

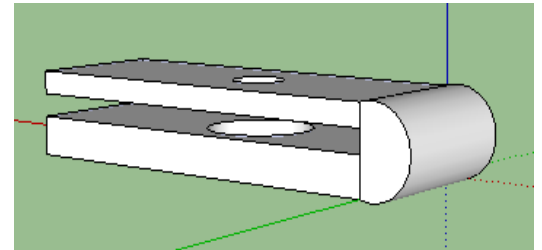


Figure 9. The notched holes that the nozzle of the aerosol can rests in are shown

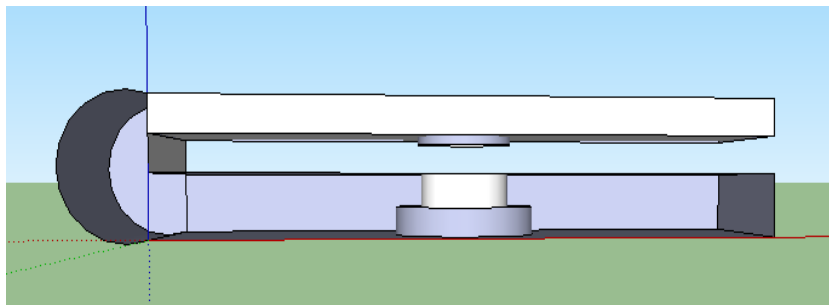


Figure 10. The vertical hole through the clamp design

As with any device, the clamp design has several pros and cons associated with it. The clamp design has the potential to work well in its ability to coat the outside of medical devices with silicone oil. It would reduce overspray significantly, thus reducing workplace hazards. The clamp design would also work with the current lubricant spray bottle, which is desirable. The biggest disadvantage of the clamp design is its complexity. The clamp design would require that the nozzle of the current spray can to be reengineered to spray vertically. The clamp design may also be lacking in its ability to coat the inside of medical devices with silicone oil. In addition to these faults, the sponges of the clamp design would need to be replaced after each patient in order to minimize the risk of cross-contamination.

5.3 Design 3: Enclosed Box

The enclosed box design, shown in Figure 11, features a snap on and off connection and three circular ports of entry to allow for the lubrication of the inside and outside of medical devices. The whole box would be disposable to avoid complicated cleaning procedures between patients.

The device would snap onto the top of the Rusch Silkospray bottle, which would allow the enclosed box to easily be attached and removed. The initial prototype of the box would be 3.85 cm high so that the top of the box is flush with the top of the spray nozzle, which would give the user access to the nozzle. The top surface of the box would have an opening of 1.8 cm in diameter (top opening in Figure 11), which allows the nozzle to be depressed to release the spray. The spray would be directed horizontally into the enclosure.

The three ports of entry would be placed as follows: one directly across from the spray nozzle, and two located horizontally such that the space between them is directly in the path of spray. In Figure 11, the opening directly in front of the spray nozzle is located in the far right of the drawing and one of the horizontal openings is located right behind the X-Y-Z axis marker. The second horizontal opening is located directly across the box from the horizontal opening shown. Each hole would contain a gasket closure, shown in Figure 12, which would ensure a tight seal around the various medical devices while they are being sprayed. It would also contain a pull-tab in the front hole to ensure that the spray particles do not escape the box when coating the outside of medical devices. In the initial prototype, the front opening would be 0.9 cm in diameter, and the two horizontal openings would be 1.5 cm in diameter. The total length of the box would be 11.1 cm and a width of 7.6 cm.

To spray the inside of tubes, the tube opening would be held up to the hole across from the nozzle. When the nozzle is depressed, the spray would leave horizontally from the nozzle and be directed into the inside of the tube. The tube is kept within the packaging so that the spray does not exit the other side of the tube and escape into the outside environment. To coat the outside of the medical devices, the device would be inserted horizontally into the two horizontal

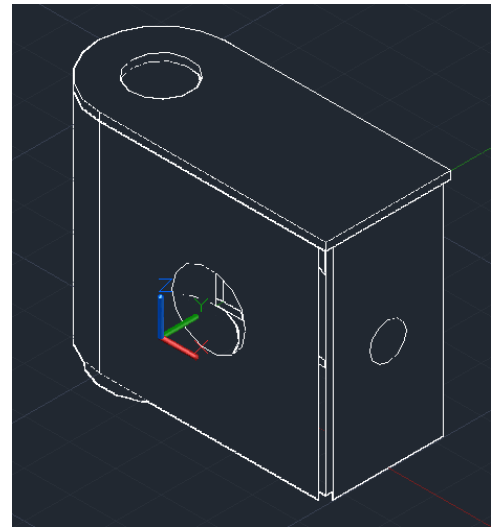


Figure 11. Enclosed box design

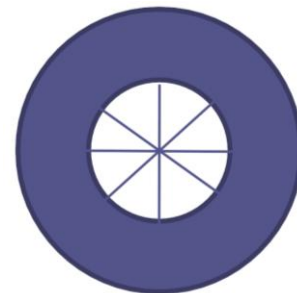


Figure 12. Gasket design for holes in box design

openings. The nozzle is depressed while the device is pulled through the box, thereby coating the entire outer surface with silicone oil.

This design has several advantages and disadvantages. This design is ideal in that it would minimize the overspray. This would reduce both the particles that are released into the air that can be inhaled, and the hazards associated with the silicone oil falling on the floor and creating a slippery surface. The enclosed box design could also coat both the inside and the outside of medical devices. Since the enclosed box is disposable, cross-contamination is not an issue. A disadvantage of this design is the possible instability of the can due to the enclosed box located on top of the canister of silicone oil spray.

6.0 Design Evaluation

In order to choose the final design, a design matrix was created to examine six different aspects of each design (see Table 1). Each aspect was weighted differently based on client requirements with a maximum score of 100 points. The first category was compatibility with the current spray container. This examined whether the current spray would need to be remanufactured for the design. All of the designs work with the current spray; however points were deducted from the clamp design because it would require a new cap that sprays vertically instead of horizontally. The maximum score in this category was 20 points.

Table 1. The design matrix evaluating the disposable pads, clamp, and enclosed box designs. The enclosed box design received the highest score; therefore, it was chosen as the final designs.

Criteria	Weight	Disposable Pads	Clamp	Enclosed Box
Compatibility with Container	20	19	14	20
Contain Spray	20	20	16	18
Ease of Use	10	7	7	9
Portability	10	7	9	9
Coat Inside	20	15	10	19
Coat Outside	20	20	20	20
Total	20	88	76	95

The ability of the device to contain the spray was also examined and also had a maximum score of 20 points. Two of the three hazards the current method creates are caused by the aerosol particles not being properly contained; therefore, it was crucial that the design eliminates this problem. Although they would be covered by gaskets, the holes in the enclosed box design could leak some of the particles. The clamp design is not completely closed, so leaking could be an issue with this design as well. On the other hand, the disposable pad design contains a completely enclosed canister causing it to receive the highest score in this category.

The final design should be easy to use, so this aspect of each design was included in the matrix. Although the enclosed box design could have some balance issues, it is the simplest design, so it was given the highest score. The clamp requires the pads to be changed for each patient, and the hook of the disposable pad design may be hard to work with, so these designs were marked down in this category. The maximum score in this category was 10 points.

Because the space in the operating room is limited, the final design must be small and be able to be stocked in the operating room. The disposable pads' canister would occupy the most space in the operating room, so it was marked down in this category. The clamp and enclosed box designs occupy less space and can be stocked in the drawers in the operating room, so they were given a higher score.

The current spray's function is to coat the inside and outside of various medical devices; therefore, the design must also be able to do this for a variety of lengths and dimensions. The disposable pad design uses the hook to coat the inside of the tubes. The complications associated with this mechanism caused points to be deducted in this category for this design. Although a mechanism for the clamp design to coat the inside of the medical tubes was created, it is unclear whether or not it would be effective; therefore, half of the possible points were deducted from the clamp design. The enclosed box has the best method for coating the inside of the tubes, so it received the highest points. The maximum points available for coating the inside was 20 points. All three of the designs are able to coat the outside; therefore, all three were given the maximum score of 20 points.

The scores from each category were summed together, and the enclosed box design achieved the highest score of 94/100. The disposable pads design and clamp design achieve 89/100 and 76/100 respectively; therefore, the enclosed box design was chosen as the final design.

7.0 Final Design

The enclosed box design fulfills all of the client's needs in the most efficient manner of all three designs, so it was chosen as the final design. The enclosed box design is disposable, coats the inside and outside of medical devices, and eliminates the danger of inhaling silicone oil particles along with the hazard of a slippery work environment. The final prototype and product will be manufactured in two halves that will be glued together, which will allow the device to be injection molded and reduce production costs. Three prototypes have been produced using 3D printing, and a fourth prototype has been drawn in Autodesk Inventor Professional.

7.1 First Prototype

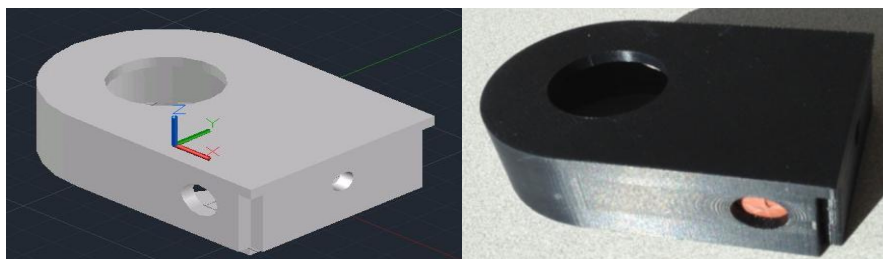


Figure 13. 1st prototype of the enclosed box design. On the left, the Auto CAD drawing and on the right is the physical prototype made of ABS plastic.

Figure 13 shows the first prototype along with an Auto CAD drawing of it. The first prototype was constructed using 3-D printing. It is made of acrylonitrile butadiene styrene

(ABS), and the gaskets are made of gum rubber. The openings to coat the outside of devices are 14 mm in diameter, and the opening to coat the inside has a diameter of 9 mm. The gaskets are able to contain the spray within the box and allow medical devices to slide through them allowing the outside of the devices to be coated in silicone oil. The gaskets follow the design shown in Figure 12. The overall dimensions of the first prototype are 97.9 mm X 67.0 mm X 34.0 mm.

Several issues were present with the first prototype. Overall, the prototype is too short, so when the can is sprayed, the silicone oil hits the top lip of the prototype instead of traveling fully into the box. The prototype is also too long causing the hole for coating the inside of devices to be too far away from the spray nozzle; therefore, the inside of medical devices cannot be sufficiently coated with silicone oil. The opening on the top of the box has a diameter of 3.4 cm, which is too large and allows the spray to escape into the external environment. The hole that allows the box to snap onto the can has a diameter of 6.5 cm, which is too large so the box does not properly fit onto the can.

7.2 Second Prototype

A second prototype was constructed using 3-D printing with the intention of solving the issues with the first prototype. The second prototype's body is made of ABS plastic and the gaskets are made of gum rubber. The final dimensions are 83.3 mm X 68.1 mm X 46.3 mm making it smaller than the first prototype. The opening on the top is reduced to 17 mm in diameter, thereby solving the problem of particles escaping into the external environment through this hole. The distance between the opening for coating the inside of devices and the spray nozzle is also shorter in the second prototype than in the first prototype. In order to raise the height of the enclosed box while keeping the nozzle accessible to the user, a step is incorporated into this prototype. Directly over the can, the box has a height of 3.9 cm, then it steps up to 4.6 cm. This prevents the spray from directly hitting the top of the box. The diameter of the opening that connects to the can is reduced to 6.2 cm and rings are added to this hole allowing it to snap onto the can. This allows the device to securely fit onto the top of the can without the user having to hold the device. See Figure 14 for the Auto CAD drawing and photograph of the second prototype.

Although the second prototype did eliminate many of the issues with the first prototype, problems in the second are still present. The opening for coating the inside of devices is not properly aligned with the nozzle, so the spray does not efficiently leave this hole. The material for the body is too stiff making it difficult to snap the prototype onto and off of the can. The step down is not large enough, so the nozzle of the can is hidden inside the box making it difficult to dispense the silicone oil. The material for the gaskets is too thick and stiff to allow devices to

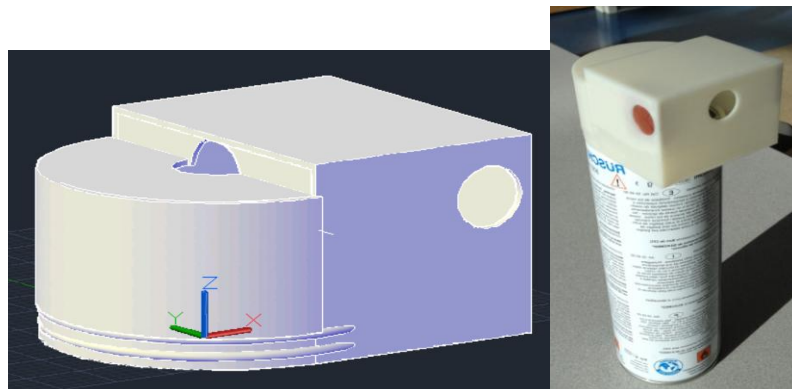


Figure 14. Second prototype of the enclosed box design. On the left is the Auto CAD drawing and on the right is the physical model attached to the silicone spray can.

easily slide through them. Also, the enclosed box contains sharp edges, which are not suitable for the operating room. A third prototype was made in the with the intention of eliminating these problems.

7.3 Third Prototype

The third prototype was created using Autodesk Inventor Professional and constructed using 3-D printing. The third prototype is designed to be injection molded while still maintaining the functionality of the second prototype. The prototype is made of ABS plastic, and has the overall dimensions of 69 mm X 46 mm X 83 mm. It is shown below in Figure 15.



Figure 15. Pictures of the third prototype. The left picture is the top down view of the bottom piece. The middle picture is the bottom up view of the top piece. The right picture is the two pieces together to make the box.

The overall design was largely similar to the second prototype, with several improvements. The third prototype features tapered sides, which allows it to be removed from an injection mold. The prototype consists of two pieces in order to create a product that is both easier and cheaper to injection mold. In order to create the final box, the two pieces will be glued together. All sharp edges and corners have been removed, as well as the step featured on the second design. In place of the step, a gradually sloped surface is used to maximize the area of the spraying chamber and ensure that the nozzle can be depressed. The nozzle hole has a diameter of 18 mm in order to accommodate the nozzle. The three tube holes have a diameter of 15 mm. The wall thickness of the third prototype is 2 mm.

Unfortunately, the third prototype still has some flaws. Most notably, the hole that the Rusch Silkospray is inserted into is too small, so the box is unable to snap onto the can. This prevents the third prototype from being tested; however, it shares the same basic design features with the second prototype, so the testing results are likely be similar. Currently, the holes on the sides of the box are too close to the front of the box, which prevents even coating of the medical devices. The third prototype has a wall thickness of 2 mm, but eventually the thickness will be changed to 1 mm in order to cut down on material costs.

7.4 Fourth Prototype

A fourth prototype was designed in an attempt to fix the flaws associated with the third prototype. The fourth prototype is essentially the same product as the third prototype with a few minor changes. The overall dimensions of the fourth prototype are 70.5 mm X 46 mm X 85 mm. The biggest change is that the size of the can hole has been increased to a 65 mm diameter, which enables the device to snap onto the Rusch Silkospray can. The wall thickness has been reduced to 1 mm, which reduces the material costs. The side holes have been moved towards the can in order to allow for more even coating of the medical devices. Furthermore, the front hole's diameter has been increased to 15.5 mm. All of the medical tubing that the clients use contain a

15 mm adaptor, so this wider diameter allows all of the tubes to snap into the box when coating the inside of the them. Lastly, a tongue has been added to make the product more stable. Instead of having the two pieces simply meet and be glued together, an inner tongue has been added so that, once glued together, the final product will be able to withstand greater forces. Printing and testing of the prototype will be done in the future. Figure 16 shows the Autodesk Inventor Professional drawing of the fourth prototype.

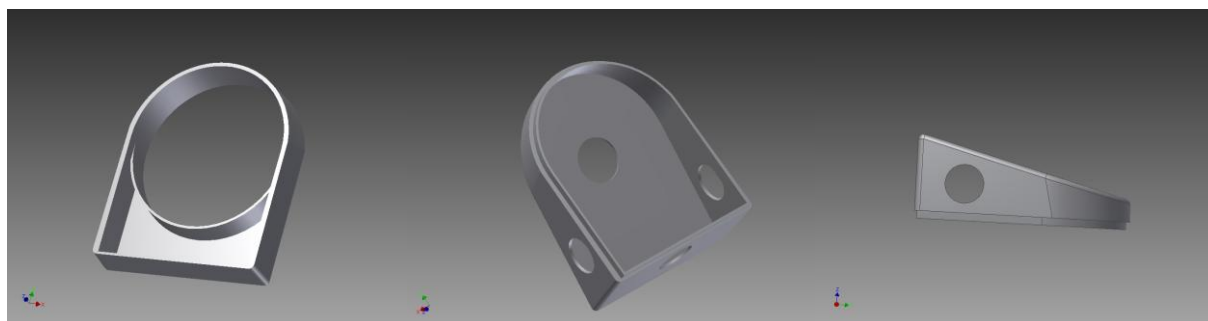


Figure 16. Autodesk Inventor Professional images of the fourth prototype. The left picture is a top down view of the bottom piece. The middle picture is a bottom up view of the top piece. The right picture is a side view of the bottom piece.

8.0 Material Selection

8.1 Body Material Selection

Multiple materials were examined as possibilities for the body of the box. They include polycarbonate (PC), poly(methyl methacrylate) (PMMA), high density polyethylene (HDPE), low density polyethylene (LDPE), polyethylene terephthalate (PET), acrylonitrile butadiene styrene (ABS), and polypropylene (PP). Various properties for these materials are shown in Table 2. The Rusch Silkospray cap is made of PP, so this was used as a basis for comparison. A design matrix was constructed to compare the different materials as possibilities for the final product (Table 3). The cost, FDA approval, transparency, and Young's modulus were compared for each material, and the highest score a material could receive was ten.

Table 2. Material properties for possible body materials (Alibaba Inc., 2012) (Boedecker, 2012) (Röchling Engineering Plastics, 2011) (Elastomers, 2009) (Commodity Polymers, 2009) (Engineering Polymers, 2009).

Material	PC	PMMA	HDPE	LDPE	PET	ABS	PP
Class	Amorphous	Amorphous	Crystalline	Crystalline	Crystalline	Crystalline	Crystalline
Density (kg/m ³)	1200	1170-1200	940-965	910-928	1370	1060-1080	902-906
Tensile Strength (MPa)	65-75	48-76	20-32	8-12M	70	41-60	30-38
Elongation (%)	80-110	2-10M	180-1000	600-650	130	5-25M	200-700
Young's Modulus (MPa)	2000-2400	1800-3100	600-1400	200-400	3100	2275-2900	1100-1550
FDA Approved	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Cost (\$/kg)	3.31-3.86	3.42-3.64	0.55-1.32	2.7-3.2	1.65-2.20	2.00-4.00	1.5-2.5

Table 3. Matrix for the possible body materials.

Criteria	Weight	PC	PMMA	HDPE	LDPE	PET	ABS	PP
FDA Approved	4	4	4	4	4	4	4	4
Cost	3.5	1	1	3.5	2	3	2.5	3
Young's Modulus	1.5	1	1.5	1.5	0.25	0.25	0.5	1.25
Transparency	1.5	1	1	0.5	0.5	0.5	0.5	0.5
Total	10	7	7.5	9.5	6.75	7.75	7.5	8.75

The material must be FDA approved otherwise it cannot be used for this application, so this category was weighted the highest with a maximum score of four points. All of the materials are approved by the FDA, so they all received four points.

Cost was worth 3.5 points because the client wants the final product to sell for five dollars or less; thus, it is essential that a low cost material is selected. From Table 2, it can be seen that the HDPE is the cheapest material, and therefore, it received 3.5 points. PC and PMMA are the most expensive materials; therefore, they received the lowest scores in this category of one point.

Ideally, the body of the box should be transparent because this will make it easier to run the medical devices through the box. This category was worth one point. PC and PMMA are amorphous at the temperatures that are required for injection molding, so they received a score of one. All of the other materials are crystalline at these temperatures (See Table 2), so they received 0.5 points.

Young's modulus for each material was examined and viewed as a representation of the material properties for each material. As previously stated, PP was used as a basis for this comparison because the current cap is composed of this. PP is too flexible for this application, so a material with a higher Young's modulus than PP is desired for the box. HDPE and PMMA have the ideal Young's modulus for this application, so they received the score of 1.5 points. LDPE and PET have too small of a Young's modulus, so they received the only 0.25 points.

Based on all of the categories, HDPE received the highest overall score of 9.5/10, so the body of the box will be made of HDPE.

8.2 Gasket Material Selection

The gasket has an inherently different function than the box; therefore, it needs to be made of a different material than the box. Polytetrafluoroethylene (PTFE), neoprene, silicone rubber, and nitrile rubber were selected as possible candidates for the gasket material. Table 4 contains the material properties for each of these materials. A design matrix was constructed to compare the different aspects of the materials (Table 5). The cost, FDA approval, and Young's modulus were weighted, and the highest score a material could receive was ten.

Table 4. Material Properties of possible gasket materials (Alibaba Inc., 2012) (Boedecker, 2012) (Röchling Engineering Plastics, 2011) (Elastomers, 2009) (Commodity Polymers, 2009) (Engineering Polymers, 2009) (Neoprene rubber, 2012).

Material	PTFE	Neoprene	Silicone Rubber	Nitrile Rubber
Density (kg/m ³)	2150-2200	960	1250	1000
Tensile Strength (MPa)	25-36	6-10	5-8	2-5
Young's Modulus (MPa)	410-750	0.081	1-5	10-20
Elongation (%)	350-550	450-550	200-800	200-500
Price (\$/ft ²)	1.42	4.5	1.27	2.32

Table 5. Matrix for the possible gasket materials.

Criteria	Weight	PTFE	Neoprene	Silicone Rubber	Nitrile Rubber
FDA Approved	3.5	4	1.5	4	4
Cost	4	3	1	3.5	2
Young's Modulus	2.5	0.5	0.5	2.25	2
Total	10	7.5	3	9.75	8

The material must be FDA approved because it comes into direct contact with medical devices. This category was worth four points. Silicone rubber, nitrile rubber, and PTFE are all FDA approved so they all received four points. Neoprene is FDA approved but only for braces, which does not apply to this application. More research would have to be done on this material; therefore, it received the lowest score of 1.5 points.

Cost was worth of 3.5 points because the enclosed box must have a low production cost. Silicone rubber has the lowest cost, so it was given the highest score of 3.5 points in this category. Neoprene is the most expensive, so it received the lowest score of one point.

The material for the gasket should have a relatively low Young's modulus because it needs to be able to conform around medical devices. This category was worth 2.5 points. Silicone rubber has the most ideal Young's modulus for the gasket (See Table 4), so it was given the highest score of 2.25 points. PTFE has the highest modulus, and therefore, it was given a score of 0.5 points. Also, neoprene has too low of a Young's modulus, so it also received 0.5 points.

Silicone rubber received 9.75/10, which was the highest score of all the materials. Silicone rubber will be the material used for the gaskets. To save on manufacturing and ordering costs, the pull tab for the box will also be made of silicone rubber.

9.0 Testing

In order to evaluate the effectiveness of the enclosed box, tests were conducted using the second prototype. The area the spray covered inside the tubes, the distance the spray travels, the reduction of the overspray were all tested using this prototype.

9.1 Area Covering the Inside of Tubes

The enclosed box was designed to streamline the spray when coating the inside of the tubes. Streamlining the spray would reduce overspray, which is the client’s main concern. To test this, newspaper was held directly against a wall and the silicone oil was sprayed for three seconds from a distance of 15.2 cm from the wall. The area that spray covered on the newspaper from the hole directly in front of the nozzle was calculated by idealizing the area as an ellipse. The spray pattern is shown in Figure 17. The test was conducted three times with the second prototype attached, and three times without the prototype. The average area covered without the prototype was 85.18 cm², and the average area with the prototype was 42.58 cm². The prototype reduced the spray area by 50 percent, thereby suggesting that the prototype streamlines the spray.



Figure 17. Spray pattern on the newspaper for the first test.

9.2 Distance the Spray Travels

The design must be able to coat tubes up to 35 cm in length. Tests were conducted to compare how far the spray could travel with and without the second prototype attached to the can. Vinyl tubing was held against the opening for coating the inside of tubes, and the can was sprayed for three seconds. The distance the spray traveled in the tube was determined. The test was conducted a total of three times with the second prototype and repeated an additional three times without the box. For the trials without the box, the tubing was held directly against the nozzle. The results of the tests are shown in Figure 18. The average area traveled without the box was 37 cm and with the box was 37.08 cm. Because the current spray is able to adequately coat the inside of medical devices, and the spray leaving the second prototype traveled almost the same distance, the enclosed box should be able to adequately coat the inside of medical tubes.

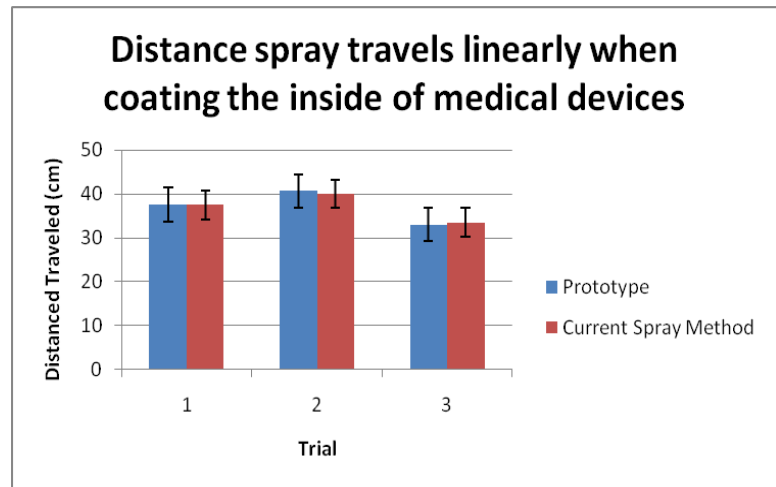


Figure 18. Graph representation of the tests to determine the distance traveled with and without the prototype. Standard deviations are reported as

9.3 Overspray Reduction

Tests were also conducted to determine how much overspray the enclosed box design reduced when coating the outside of medical devices. The can was placed on the floor, sprayed, and the longest and widest distances the spray traveled were determined. The area the spray

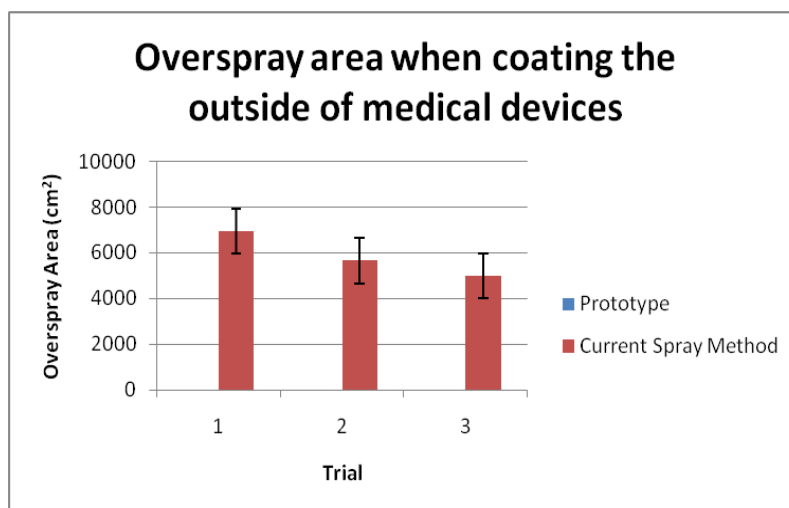


Figure 19. Test results of the overspray areas, The standard deviations are reported as error bars.

covered was found by idealizing it as half of an ellipse on top of a triangle. The test was conducted a total of three times, and also conducted three times with the second prototype attached. The results of the tests can be seen in Figure 19. The average area without the second prototype was 0.59 m^2 and with the prototype was 0 m^2 . These results suggest that the enclosed box completely contains the overspray.

A test was also conducted to determine if the enclosed box was able to adequately lubricate the outside of medical tubes. A vinyl tube was run through the box while spraying the silicone oil. The tubing did become lubricated; however, quantitative results could not be measured because the gaskets are not made of the correct material. Further testing will be conducted on this important aspect on fourth prototype.

10.0 Injection molding

As previously mentioned, the final product will be injection molded to allow for large scale production. An injection mold quote was sought from 3 different sources: the mechanical engineering (ME) laboratory, a local injection mold company, and an oversea manufacturing complex. Several meetings were held with the UW-Madison ME department polymer center laboratory. The lab could provide free use of a CNC machine where the only cost of manufacturing the molds would be from materials and tooling. The cost of the molds through this source would be under \$1000, which is within the project budget; however, this would be extremely time-consuming and would significantly delay the prototyping process. Another potential source came from the local injection mold company Apollo Tools Inc. The local firm could manufacture the molds within 8 weeks and provide warranty and immediate repair services for the molds; however, the injection molds would cost \$19,600 to produce (See Appendix C), which is more than \$18,000 over budget. As another option, a quote was obtained from an oversea manufacture complex, Zhenyuan Injection Molding Inc., in Shenzhen, China. The company could produce the molds for approximately \$8,000, which is \$7,000 over budget. (See Appendix C). They would also not be able to provide a warranty and repair services for oversea costumers. Further testing of the prototypes needs to be completed before any forward action can be taken in constructing the molds.

11.0 Future Work

In the upcoming weeks, the fourth prototype will be 3-D printed with ABS and tested. Silicone rubber has been purchased and will be used to construct the pull-tab and gasket for the fourth prototype. If the testing results are significant, the clients will conduct their own testing of the fourth prototype. In the meantime, the design has been entered into the Burrill Business Plan Competition in April.

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**Appendix A:
Product Design Specification Report
Silicone Oil Applicator for Medical Devices**

Date: 14 December 2011

Team:

Kimberli Carlson-Team Leader
Tian Zhou-Team Communicator
Claire Wardrop-BSAC
Ryan Nessman-BWIG

Problem Statement

Our clients, Drs. Richard Galgon and George Arndt, of the UW-Madison School of Medicine and Public Health, Department of Anesthesiology, work as anesthesiologists at the UW-Hospital. Currently, surgeons and doctors (anesthesiologists, pulmonologists, critical care medicine physicians, and emergency room physicians) use an aerosolized medical grade silicone spray to lubricate certain upper airway tubes, catheters, and bronchoscopes in the operating room, pulmonary suite, intensive care unit, and emergency room, to allow the devices to slide over one another. The devices include, but are not limited to: fiberoptic bronchoscopes, single and double lumen endotracheal tubes, airway exchange catheters, Aintree intubation catheters, laryngeal mask airways and other supraglottic airway devices, bronchoscope and airway circuit adapters, and bronchial blockers. Although the aerosolized silicone oil sufficiently lubricates these medical devices, the current application technique poses three main problems: (1) creates a slippery work environment, presenting a risk of injury to personnel and patients, (2) poses a risk for cryogenic burns (frostbite), and (3) releases particles into the air that can be inhaled. A different effective method of applying the silicone oil lubricant to these devices that eliminates these problems is sought.

Client requirements

Alternate method of applying the silicone oil must:

- Make use of current aerosol spray-Rusch Silkospray
- Not allow lubricant into external environment
- Prevent hazardous work conditions
 - Eliminate slippery surfaces outside of intended device
 - Protect users from cold effects
 - Protect users from inhalation of particles
- Be able to deliver lubricant inside various tubular medical devices
 - Internal diameter of tubes from 2.5mm to 9mm
- Lubricate the outside cylindrical medical devices:
 - External diameter of tubes up to 13.7mm

- Length of device up to 35cm long
- Allow for fast application of lubricant
- Coat target area of device evenly
- Not interfere with other hospital equipment
- Be portable within the hospital
- Have a low cost
- Be mass producible
- Be disposable for each patient
- Take up a minimum amount of space
 - Less than 10cm x10cm x 10 cm

Design requirements:

1. Physical and Operational Characteristics

a. *Performance requirements:* The device will be used to lubricate the inside of medical tubes and the outside of cylindrical tubes and equipment. The device must allow the lubricant to reach all areas of the surface of the equipment to which it is being applied.

b. *Safety:* This device must not endanger the user and others in the area. There must not be toxic materials or sharp edges within the device. The device must protect the user from cold effects of the spray and particles that may be inhaled. The device should restrict the lubricant to the intended medical device and should not allow the lubricant to get onto other surfaces, such as floors, where it may cause occupational hazards.

c. *Accuracy and Reliability:* The method and device that applies the silicone oil must coat the entire surface of the intended piece of equipment. The lubricant should ideally be evenly applied to the surface.

d. *Life in Service:* The device for applying the silicone oil must be disposable. The device will be used for a single patient surgery and will be replaced after each surgery. The total life in service shall not exceed 6 hours under normal surgical conditions.

e. *Shelf Life:* The materials of the device should not degrade over time that it would be stored until needed. The devices would be required by the hospital for usage approximately 15 times per week.

f. *Operating Environment:* The device will be used to lubricate multiple pieces of medical equipment per use. The device will be restricted to use with a single patient so there will not be cross contamination. The device will be disposable to avoid sanitation issues. The device will be used in the operating and emergency rooms.

g. *Ergonomics:* Lubrication device must be user friendly. The device must take less than 30 seconds to assemble. The lubricant must be able to be applied in less than 30 sec.

h. *Size:* The device should not exceed a size of 10 cm x 10 cm x 10 cm.

- i. *Weight*: The device should weigh no more than 3 kg.
- j. *Materials*: Materials must be safe for use with humans. Any material used should not pose a health risk. Non-radioactive, non-flammable, and non-corrosive materials should be used.
- k. *Aesthetics, Appearance, and Finish*: The device should be pleasing to the eye. The finish should be smooth and clean looking.

2. Production Characteristics

- a. *Quantity*: One device is required at this time; however, since the device may be used commercially, the device should be mass producible.
- b. *Target Product Cost*: The budget for the entire project is \$1000. Once a device is mass produced it should cost less than \$5.00.

3. Miscellaneous

- a. *Standards and Specifications*: This device may require approval by the FDA if this device is mass produced for market use. Currently, the device falls under Class I classification and does not require any premarket notification to the FDA regarding the device.
- b. *Customer*: The device would be used by doctors that are trained to properly use the device.
- c. *Patient-related concerns*: The device must not promote bacterial growth. The device should be disposable; however, since the lubricated medical devices will be used in a patient's upper airways, which are not sterile, the device does not have to be sterile. The device will not come into direct contact with patients.
- d. *Competition*: Currently there are no products on the market that are used to avoid the above mentioned problems with the aerosol spray.

Appendix B: Testing Raw Data (Second Prototype)

- 1) Data obtained from the tests determining the area when coating the inside of medical tubing.

Table B1. Results of the tests determining the area covered on the inside of tubes.

Trial	Dimensions (cm)		Area (cm ²)	
	Prototype	Current Spray	Prototype	Current Spray
1	4.4 x 5	6.8 x 8	34.56	85.45
2	5.1 x 5.75	7.3 x 7.8	46.06	89.44
3	5 x 6	7.9 x 6.5	47.12	80.66
Average			42.58	85.18
Standard Deviation			6.965716044	4.396070215

- 2) Data obtained from the tests determining the distance the spray traveled inside the tubes.

Table B2. Results of the tests determining the distance the spray can travel.

Trial	Distance (cm)	
	Prototype	Current Spray
1	37.59	37.5
2	40.64	40
3	33.02	33.5
Average	37.08	37
Standard Deviation	3.835315893	3.278719262

- 3) Data obtained from the overspray tests.

Table B3. The lengths and widths found from the overspray tests.

Trial		Prototype (cm)	Current Spray (cm)
1	Length	0	204.47
	Width	0	53.34
2	Length	0	199.39
	Width	0	44.45
3	Length	0	190.5
	Width	0	41.91

Table B4. Areas calculated for the overspray tests.

Trial	Area (cm ²)	
	Prototype	Current
1	0	6942
2	0	5661
3	0	4995
Average	0	5866
Standard Deviation	0	989.555961

Appendix C. Quotes from Mold Manufacturers



深圳市圳远塑胶模具有限公司

Shenzhen zhenyuan plastic mould co.,Ltd

(Specialized in precision mould and injection plastic parts Manufacturing)

Address: Sha Pu industrial area ,Song Gong Town, Shen Zhen



Tel :00-86-755-81730226 Fax :00-86-755-27052499

Web site: <http://www.szzhenyuan.com> Mail: jacky@szzhenyuan.com

To	: SOA project design group	Date	: FEB 24,2012
Attn.	: 周天	Fax No.	:
From	: Jacky /18665833735	Country	: China
C.C.	: Zhang VP	Page	: Total 1 pages

Re :Quotation of project 22400111

Thanks for your inquiry of the captioned, we would like to offer you the best price as follow:

Item.	Drawing no.	Description Material	CAV	Tooling Charge (RMB)	U/P (RMB)	Moq
TOP		ABS	1	¥39,000	待最后结构定	2kpcs
BOTTOM		ABS	1	¥22,500	待最后结构定	2kpcs

----The material for this quote is ABS with your requirement. Material is certificated by ROHS.

----U/P quoted is based on your pro-e drawing, if you updated your drawing, we will revise quotation.

----1 shot free sample will be provided after the tool is completed.

----Mold material is NAK80 and standard is LKM.

----Mold life is more than 300K cycles.

REMARKS:

The above quotation is based on the terms & conditions specified as below:

1. Tooling payment terms: 50% paid in advance, 50% paid after mould is AP.
2. Product payment terms: Invoice 30days
3. The above quote is valid for 30 days without any vat.
4. U/p and tooling charge is based on your pdf Drawing. it will adjust if the drawing or process will be changed.
5. Tooling L/T is 24 days, also is calculated upon the receipt of your tooling order and final drawing.
6. Production L/T :
 - a) New order is 2 weeks after tooling approval
 - b) Repeat order is 1 weeks.

APOLLO QUOTE #: A5784

DATE QUOTED: February 22, 2012



ATTENTION: Tian Zhou

CUSTOMER: University Of Wisconsin

PART DESCRIPTION: Silicone Applicator Top & Bottom

PART #: TBD

END USER: N/A

CAD FILE NAME:

CAVITATION: 1+1

Silicone Applicator Top & Bottom

Two Cavity 1+1 Family Thermoplastic Injection Mold
 Design & Build-----\$ 19,600.00 Delivery: 8 Weeks

Construction Notes:

- Quoted both details to be machined directly into P-20 "A" & "B" plates
- Three slides are required for the Top part. Slides to be S-7 Steel
- Minor part changes could be required. Draft etc.

TYPE OF CONSTRUCTION:

- 1) Thermoplastic Injection Mold
- 2) Cold Sprue / Sub Gate
- 3) 3-Slides (Top Part)
- 4) Mold Base Locks
- 5) Pin Ejection
- 6) Guided Ejection
- 7)
- 8)

FINISH:

CAVITY:	Fine EDM
CORE:	C-3
SLIDE:	C-3
TEXTURE:	N/A

TYPE OF MATERIAL:Material Notes

MOLD BASE: #2

CAVITY: P-20 "A" Plate

CORE: P-20 "B" Plate

SLIDES: S-7

THANK YOU FOR THE OPPORTUNITY TO QUOTE.

MARK A. MILBRANDT