School of Mechanical Engineering

ME 557 --- Design for Manufacturability: Theory and Applications

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Insufflator Redesign Project

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Abstract

The purpose of this project was to analyze an existing design of some device that is in production or in use today. Then, the object was to improve this design based on the analysis tools and standards explored in ME 557: Design for Manufacturability. This report details the process steps behind this analysis of an Insufflator device made by Covidien. It will also describe the ultimate redesign concept developed after exploring the potential improvements that could be made to the original design based on assembly, manufacturing, and customer considerations. In conclusion to the project, it was found that a significant amount of components were not necessary, or could be combined into other components. Overall, an estimated $350,000 per year could be saved in device construction based on the redesigned concept.

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Introduction

The Insufflator is a currently designed medical device, produced by Covidien, used in laparoscopic surgeries. During laparoscopic surgeries, incisions are made on the abdomen wall. The abdomen is inflated, and endoscopic instruments are introduced. For this process, a reliable and clean channel connecting the abdominal cavity and external environment is necessary. The Insufflator device provides this channel for the main purpose of inflating and deflating the body cavity. The device also doubles as a trocar device intended for the insertion of endoscopic instruments into the cavity.

Figure 1: Covidien Insufflator Design (With Balloon Inflated)

Figure 1 shows the current design of Insufflator. The following functions and requirements are achieved:

1. To create a channel through the abdominal wall, lock itself in the position and seal the incision.
2. To allow gas to pass into to insufflate the abdomen.
3. To allow gas to flow out to desufflate the abdomen.
4. To allow endoscopic instruments introduced and removed through the trocar sleeve.
5. All the surfaces that may contact the patient have to be made of bio-compatible material.
6. The device must be able to inflate the body cavity and maintain the body inflation.
7. The device must seal the body cavity from the inside and outside to minimize the deflation rate.
8. The device must have a minimum clearance of 10 mm inner diameter to allow for varying size range of instruments to be inserted through the cannula.
9. The method of sealing the device from air leakage must be as gentle to the patient as possible.
10. The sponge location must be adjustable and lockable.

The procedure of insufflation is shown in Figure 2, followed by a detailed description of the process steps. The parts referred to in this list are defined in Table 1.

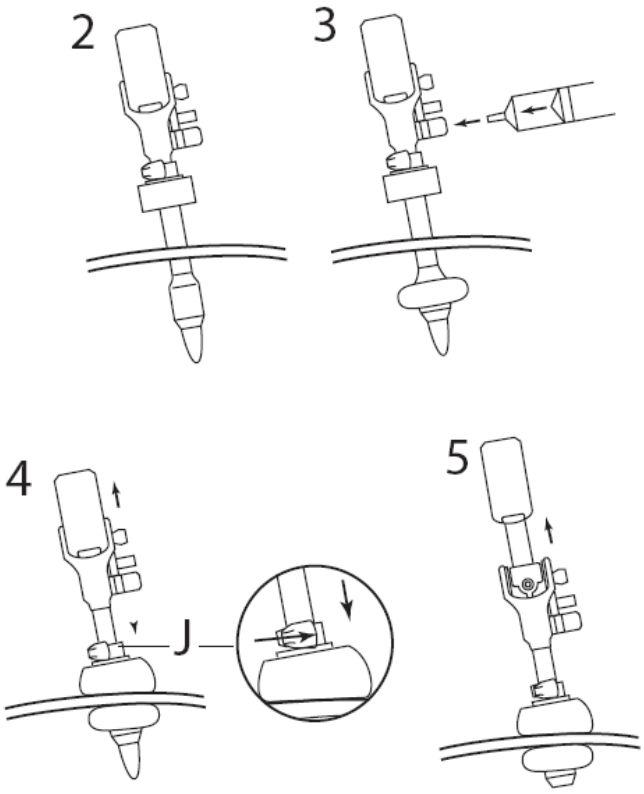


Figure 2: Insufflation Procedure

1. Make a small incision in the abdominal wall. Carefully dissect the tissue down to, and through, the desired tissue plane.
2. Introduce the Blunt Tip Trocar into the incision to the desired place.
3. Inflate the balloon through the balloon inflation port with 25 ml of air.
4. Pull back the cannula assembly until resistance from the inflated cannula balloon is felt. Slide the foam sponge/collar down to the skin, compressing the foam. Lock the sponge collar into place.
5. Remove the obturator.
6. If insufflation is desired, attach the gas line to the one-way valve using a male luer lock/adapter. Endoscopic instruments may be introduced and removed through the trocar sleeve. The flapper valve is opened by pushing the button on the valve assembly.
7. Converters are included on the valve body of the Blunt Tip Trocar to allow insertion of instruments of various sizes. The size of each converter is marked on the converter. To use, slide the converter from the side of the valve body, and firmly push it over the main seal until reaching a positive stop.
8. Upon completion of the procedure, the abdominal cavity may be deflated by opening the flapper valve.
9. To remove the Blunt Tip Trocar, place the syringe in the balloon inflation port with the plunger free to move. The balloon will deflate, pushing the plunger out and filling the syringe. Remove the Blunt Tip Trocar.

Unfortunately, the current design has some problems. The main problem is the leakage of balloon, which is hard to detect and can lead to relatively serious consequences. During the surgery, only 25 mL air is inflated into the balloon, even a small leakage can cause a flat balloon. If it happens, the insufflator might loose its sealing capability or may even fall out of the incision. As the balloon cannot be seen from outside, re-inflation during the surgery is inapplicable. Excessive inflation might cause balloon rupture. The material in the internal side of the balloon may cause allergic reactions if it contacts the patient's tissues. The leakage problem is introduced by the joint of the trocar sleeves and the body assembly. The joint is sealed by glue. The current design has potential problems that cannot be detected. The gas in the abdomen might also leak from the joint of the trocar and the cannnula. This may cause an undesired amount of desufflation during the procedure, which may interfere with operations that are conducted during surgery.

Some other problems also exist. The latch is composed by 6 parts, including 3 small pins. The pins are fixed with locational fits. The latch may snap and the pins might drop during usage. This is especially dangerous when there is an open incision in the patient. A summary of the problems that may occur are shown in Table 1

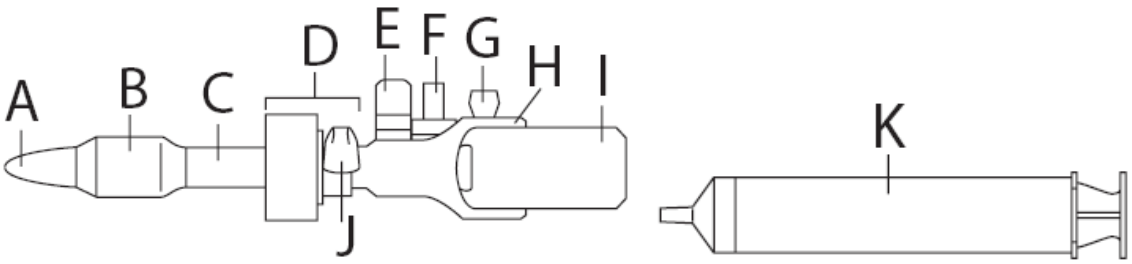


Figure 3: Construction of Insufflator

Table 1: Functions and Problems of Insufflator Components

Number	Name	Function	Problem
A	BLUNT TIP	Help to push through the incision.	
B	BALLOON	To seal the incision from inside.	Might rupture.
C	CANNULA	1. To provide path for gas to the balloon; 2. To provide path for gas to the abdomen.	
D	SPONGE/COLLAR ASSEMBLY	To seal the incision from outside.	
E	BALLOON INFLATION PORT	To allow air to pass into and inflate the balloon.	
F	ONE-WAY VALVE (for insufflation)	1. To allow gas to pass into and inflate the abdominal wall. 2. To prevent the back-flow	

		of insufflation gas.	
G	DESUFFLATION BUTTON	To open valve let abdominal air to flow out and desufflate the abdomen.	Might be stuck. Might be accidentally compressed.
H	VALVE BODY ASSEMBLY	To connect the valves and the tubes.	The connection part might leak.
I	HANDLE ASSEMBLY	To hold the blunt tip.	This assembly is not necessary.
J	LATCH	To lock the sponge/collar assembly in place.	The latch contains 6 parts. The pins may drop.
K	SYRINGE	To inflate the balloon.	

Because of the numerous problems experienced with this design, and the complexity of the assembly and number of components, a redesign of this device was called for. According to the constructions and problems of the current design, the redesign will focus on fixing the leakage problem and simplifying the design. The amount of components and the total cost will be reduced. The parts that lead to the problems shown above will be improved or eliminated. At the completion of the redesign, the strength and reliability will be verified.

Quality Function Deployment (QFD)

For determining what aspects of the current design should be addressed or modified in the redesign, a QFD exercise was performed, and a House of Quality (HOQ) was drawn up. Now, normally, the customer requirements and the engineering characteristics in the HOQ are generated through the following means:

- Brainstorming - Generation of possible customer requirements (CRs) and generation of Engineering characteristics (ECs)
- Survey - assessment of the importance of each customer requirement
- Benchmarking – determining the effectiveness of pre-existing vacuums with regard to the CRs

However, for the insufflators, customer surveys could not be performed due to the niche nature of the users and the lack of means and resources to approach them. Similarly, benchmarking of the product could not be performed because of the difficulty in procuring competitor products.

The customer requirements and the engineering characteristics were thus obtained through the following means:

- Interaction with a representative of the manufacturer of the insufflator under review
- Study of brochures/ product features advertised on the competitor websites
- Brainstorming within the group

Note: The competitor websites studied are listed as follows:

Endopath*: http://www.bio-medicine.org/medicine-products/ENDOPATH-26reg-3B-Xcel-26trade-3B-Blunt-Tip-Trocars-11276-1/*

Pajunk: *http://www.pajunk-gmbh.de/c3view.php?sid=Lw9l8qxrN1lv1ObwqbUwwW85YbW3OlfE11wNwEbw&ieb=1260553028&c3p=39&c3l=en*

Brainstorming:

Based on the group's understanding of the product after extensive discussions with the manufacturer representative and by disassembling a sample of the product, the chief functions and requirements of the insufflator were identified and written down. This in some instances included manufacturing or assembly requirements since the manufacturers can be seen as customers of the designers. From the generated customer requirements several functions had to be eliminated as irrelevant to the current project scope, or as information regarding them were unavailable.

A similar procedure was followed for identifying engineering characteristics. Through the group's understanding of the product and through the features specified in the above mentioned websites, the key characteristics were identified. Again, some of these had to be discarded due to lack of available information or because it was deemed out of the scope of the project to address them.

Benchmarking:

Though products were not available for comparison during benchmarking, a rudimentary comparison of features (based on our understanding and based on the features advertised by the competitors) yielded some understanding of how they would compare against competitors. It would be worthwhile to note that in several of the customer requirements, there was too little information to even speculate on how these features compared against the competitors. In such cases, the same rating was given to all the products.

Drawing correlations between ECs:

The ECs were filled into the house of quality and correlations were drawn between them, filling in the roof of the house. Correlations between two ECs were deemed positive when pushing one EC toward its target resulted in the other EC moving toward its target. Correlations were deemed negative when pushing one EC towards its target resulted in the other EC moving away from its target. For example, increasing the pressure rating of the balloon would improve the sealing of the insufflated body from the inside, thus reducing the leakage from the insufflated body. This is interpreted as a positive correlation between the pressure rating and the leakage from the body cavity.

Other correlations which were initially not apparent materialized upon greater scrutiny – these were the relationships between leakage and the number of components. Rationalizing this find later, it

seemed self-evident that the fewer the number of components, the fewer joints there are, and thus the fewer chances there are of a leak occurring.

Assigning relationships between the CRs and the ECs:

This exercise involved moving down an EC column and looking at how strongly there was a relationship between each customer requirement and that EC, assigning a 1, 3, or 9 based on a weak, medium, or strong relationship accordingly. This also helped identify and rule out some of the less critical ECs we came up with.

Assigning importance values to the ECs:

The absolute importance of an EC was calculated using the following formula:

Ae = (Wc1 * Rce1 + Wc2 * Rce2 + ... + Wcn + Rcen)

Where Wc1, Wc2.. are customer requirement importance weights

Rce1, Rce2... are relationship values assigned between the ECs and the CRs

The value of Ae obtained from each EC was then divided by the total of all calculated Aes to obtain the relative importance of an engineering characteristic.

Assigning target values:

Assigning target values proved to be a challenge, again because of the lack of information available. Some of the target values could be calculated based on other exercises. For example, a study of the assembly index and part reduction gave us a target value of 12 for the number of components. For others, calculated guesses had to be made – for example the pressure of air inside the balloon was assigned a target value based on our estimate of the size of the balloon when inflated and the volume of the air used to pump it up (25cc syringe). While these may not have been accurate estimates, they gave an indication of the direction our redesign needed to take.

Inferences from the House of Quality:

By studying the relative importance of the engineering characteristics, it became clear that the important characteristics were leakage rate from the joints, leakage rate from the body cavity, and the number of components in the assembly. Other engineering characteristics which are noteworthy are the pressure rating of the balloon, and the area of the instrument in contact with the user's hand, but to keep the scope of the current project realistic, the highest three characteristics were concentrated upon.

Redesign Concept

An exploded view of the redesign concept is shown in the figure below. For this design, the amount of parts has been reduced from 31 for the original design to 20. Some of the aspects of the design will remain unchanged, like the desufflation button mechanism and the balloon concept, but the overall housing and body of the design has been changed.

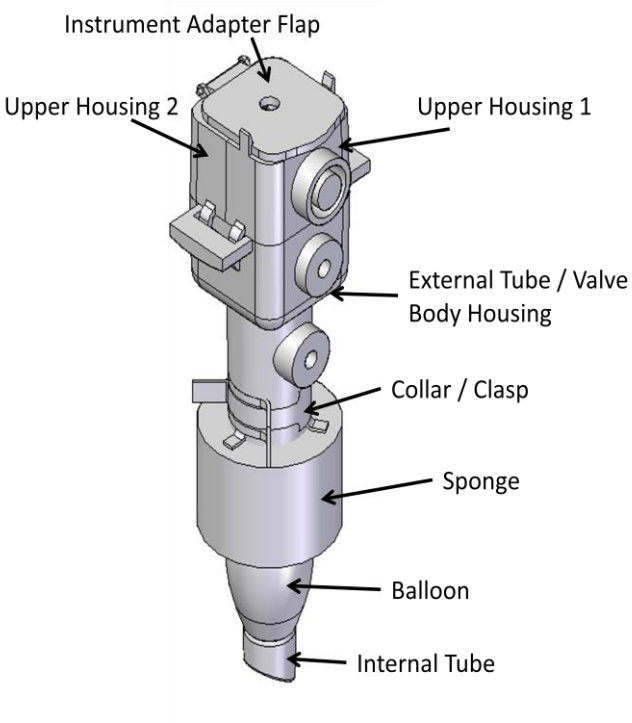


Figure 4: Redesign Concept: Overall View

As can be seen from the overall view, this design combines a lot of the components in the old design. For example, the external tube / valve body housing component is now all one piece. In the previous design, this was made from several components, all attached together by snap fits and glue. This will eliminate the problems of leakage in the new design.

Another aspect to notice about the new design is that the obturator is completely eliminated. With the new tip design, the trocar device can be inserted into the body cavity without the use of any external blunt tip component. And, because of the one way valve door flap and seal, the body cavity can remain inflated without leaving the obturator in the trocar. The handle flaps designed into the outer tube / valve body housing are intended for easy handling and maneuvering of the device by the surgeon. This replaces the function of the handle in the original design.

This device is still entirely disposable. The main idea for the redesign was to improve the existing design by reducing failures, reducing the part count, and reducing or eliminating a number of difficult assembly tasks; not to completely redesign the entire device for multiple use. For an exploded view of the design with all components labeled, refer to the Bill of Materials (BOM) in the appendix.

Unchanged Components:

There are a few components in this redesign that remain unchanged from the original design. The Balloon was one such feature. This feature remains in the design because of its simplicity, and the fact that it is relatively gentle to the tissue layer it will be in contact with. The same can be said for the sponge, which also remains in the design. These two components are intended to seal the body cavity from leakage into the atmosphere. One main reason that these two components in particular will not be changed is due to the limited amount of information that could be obtained about the product and the patient interaction. It was assumed that Covidien, being a leader in biomedical engineering, had previously conducted tests or run studies on the best method for sealing the body cavity, which resulted in this design.

The Desufflation Button mechanism design (for desufflation of the body cavity) was another component that was not altered in the design, other than to recess it into the upper housing. This design was not changed because it appeared to be a very feasible and simple design that experienced very little failures in comparison to the other features. The purpose of the recess is to prevent accidental desufflation during surgery. In the limited amount of time for completion of this project, it was decided that the larger issues required more attention. Along the same lines, the one way door flap seal was not changed also because of its effectiveness in the current design.

One Way Valve and Balloon Subassembly:

The one way valve and balloon subassembly constitutes the lower half of the device. It includes the External Tube / Valve Body Housing, the Internal Tube, the Balloon, the Clasp and the Sponge.

The Internal Tube will fit snuggly inside the External Tube / Valve Body Housing. This is depicted in Figure 5. This figure shows the upper portion of the tube resting on the interior surface of the valve body housing. This connection is intended to provide the division between the gas that inflates the body cavity and the gas that inflates the Balloon. There will be a small air gap in between the External Tube and the Internal Tube for air passage into the Balloon. The two parts will be glued together and some sort of sealant will be used to prevent gas leakage.

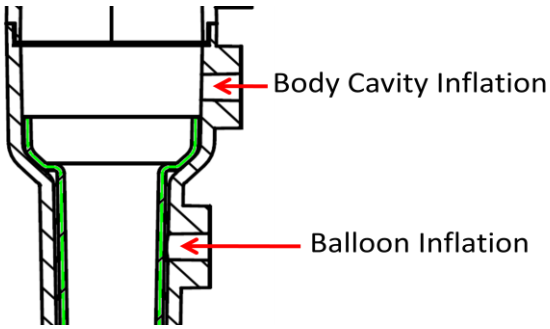


Figure 5: Internal Tube and External Tube Clearance

The Collar / Sponge assembly will fit over the External Tube, and the Balloon will be secured to the lower portion of the inner and outer tubes, using the groves in the shaft as a guide for the sutures. This is discussed later.

External Tube / Valve Body Housing:

The External Tube / Valve Body Housing is the main body of the device. Compared to the original design, it combines the External Tube and the Housing which contains the one way valves for Balloon and body cavity inflation. Combining these two parts into one eliminates some of the leakage issues as well as reduces the total number of components. The drawback with this is that the geometry of this part is slightly more complicated than exists in the current design. But, as discussed in the manufacturing and material processing section, an injection molding process can be implemented to create this geometry.

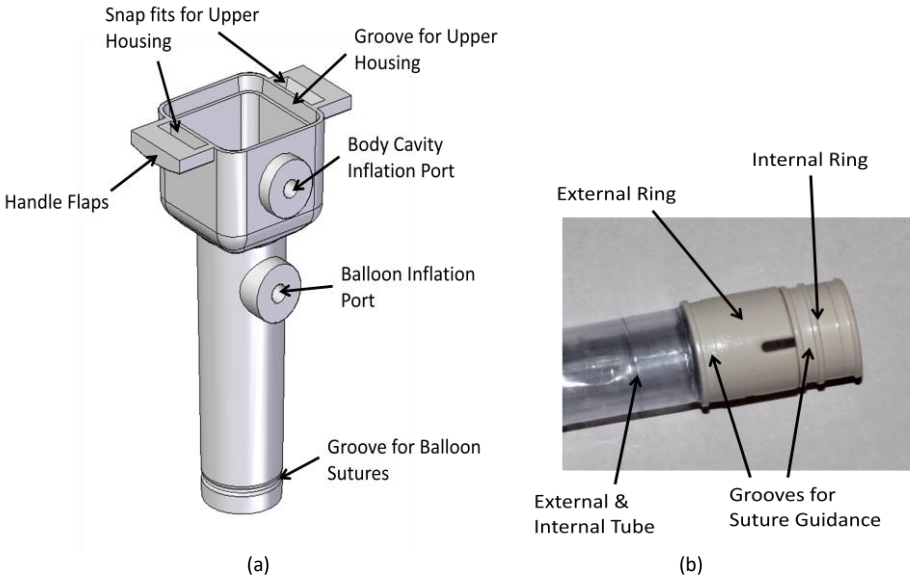


Figure 6: External Tube / Valve Body Housing: (a) new design (b) original design close-up of external and internal ring

As can be seen in Figure 6, there are a few features built in to aid in the assembly process and the quality of the overall device. First, at the top of the device, a groove was designed into the housing so that the two upper housing pieces can easily be located and secured within this component. There is also a snap fit designed into the handle flaps so that the upper housing will secure itself.

Another feature that can be observed is the external ring, intended for suture guidance when assembling the balloon, is now designed into the External Tube. This eliminates a component, a potential sealing issue, and some assembly time.

Inner Tube:

The Internal Tube is changed significantly from the previous design. It now has a little more complex geometry that will affect the forming process, which is discussed later. Since it is no longer a

pure cylindrical design, it now has a feature to provide a snug fit into the External Tube / Valve Body Housing. Also, it is designed such that it will also have a groove as the bottom for location of the balloon sutures. This eliminates the need for the interior ring on the original design.

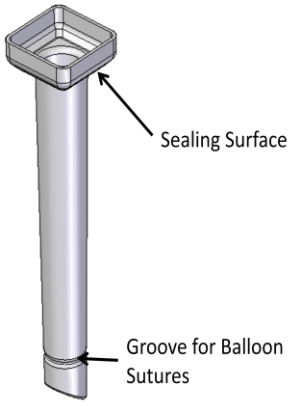


Figure 7: Internal Tube

One key aspect of this new Internal Tube design is the tip of the tube. The slant at the tip will allow the tube to penetrate the incision in the body cavity without any need for an oburator. To ensure smooth motion of the trocar past the tissue, this slanted tip with be covered by a thin membrane, made from the same or similar material to the flexible adapter flap rubber, with a small hole in the membrane to allow for air flow and tool insertion. The Figure 8 illustrates this membrane. This membrane could be attached to the tube by a similar means as the instrument adapter flap membrane. But, since the current design of the adapter flap is manufactured outside of the Covidien facility, and the process behind this is not known, the membrane could also be stretched across the cannula tip surface and sutured in a groove in the same method that the balloon will be sutured. This idea is also illustrated.

(a) (b)

Figure 8: Internal Tube Slanted Tip: (a) without thin, flexible membrane (b) with thin, flexible membrane

Balloon:

The Balloon concept is not modified for the redesign, however its implementation in the design is. The Balloon will now be sutured directly to the outside of the External Tube and the outside of the Internal Tube. This is depicted in Figure 9. As can be seen here, the way that the Balloon is attached allows for air passage between the External and Internal Tube into the Balloon for inflation.

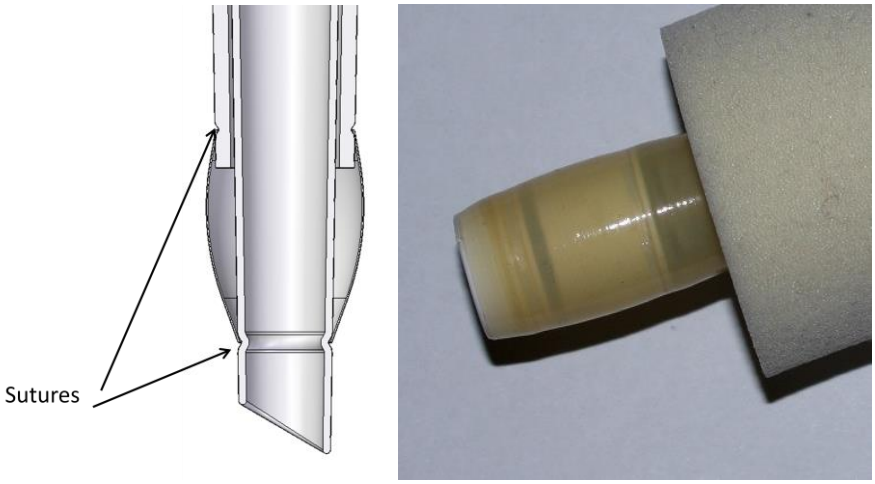


Figure 9: Balloon Attachment Method: (a) new design (b) original design

The Balloon will then be covered in the same silicone material that is used in the current design. The one disadvantage here is that the Internal tube will extend a little further than the end of the Balloon into the body cavity than the original design.

Collar / Clasp & Sponge:

The Collar / Clasp was completely redesigned due to its complexity, the number of small parts, and the amount of failures that have occurred with the original design. Now, it will be made entirely from one piece of sheet metal, as opposed to the 3 pieces of injection molded plastic and 3 pins. To move this latch up and down, the user simply squeezes the two flaps to increase the inner diameter. When there is no pressure on the two flaps, the friction between the inner surface of the collar holds the Collar / Clasp & Sponge assembly in place. The Collar will be attached to the sponge by gluing the three attachment flaps to the sponge.

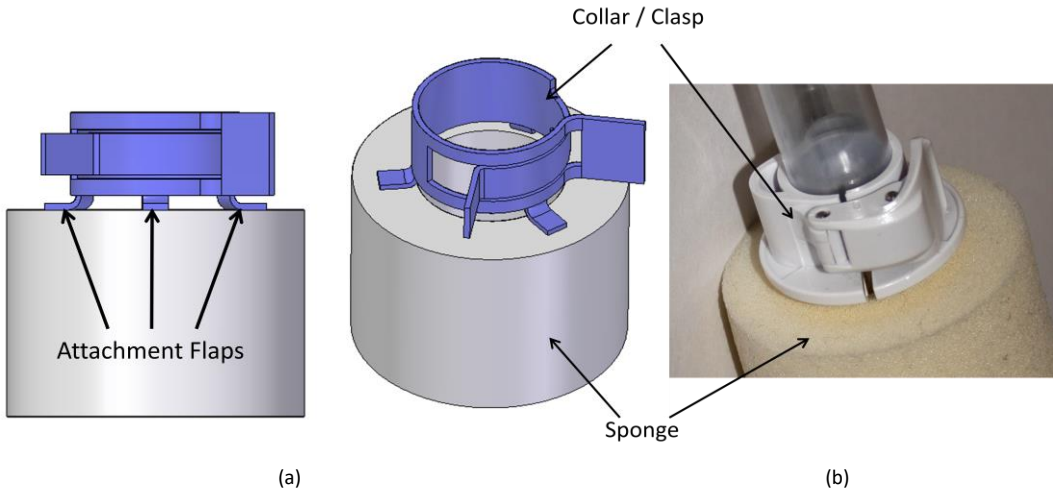


Figure 10: Collar / Clasp Design: (a) new design (b) original design

Upper Housing Assembly:

The Upper Housing assembly redesign was not changed significantly from the original design. The Desufflation Button and Valve / Door Flap mechanism remains in the design because it is necessary for sealing the Insufflator due to the elimination of the obturator. The push button is useful for deflating the body cavity at the conclusion of the surgery. The two upper housing components have very little changes, other than to fit within the new Valve Body Housing and they no longer have a connection for the body cavity inflation valve. The Instrument Adapter Flap has also been changed to provide a universal seal and is no longer part of a sliding motion. The exploded view of the components that make up the Upper Housing assembly is shown in Figure 11. What is not shown in this exploded view is actually the seal that will rest in the groove in the top of Upper Housings 1 and 2 (part number 13 on the BOM). This was not modeled because it will be the same as in the existing design. Its purpose is to prevent leakage past Valve / Door flap.

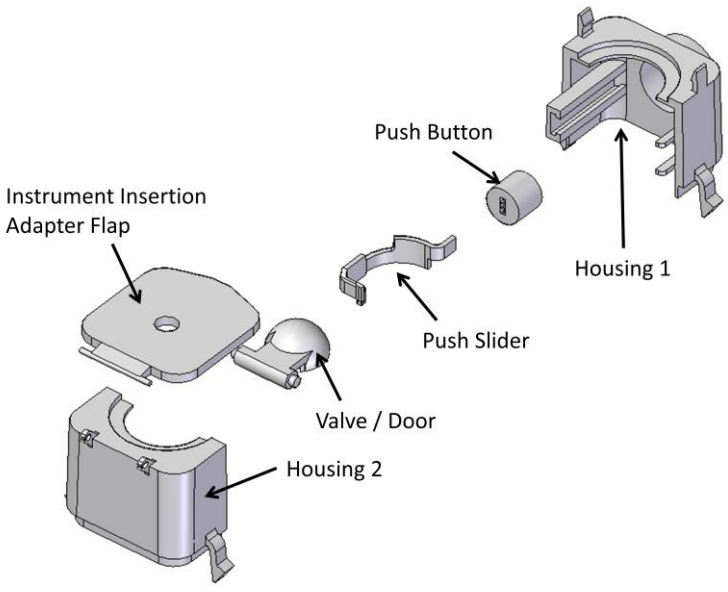


Figure 11: Upper Housing Assembly

Upper Housing:

The two upper housing pieces are only changed slightly from the original design. This is to account for the mating component that needs to be modified to fit within the new Valve Body Housing design. Also, the opening for the desufflation push button is now designed so that the push button will be recessed into housing, to prevent accidental compression of the button leading to deflation of the body cavity.

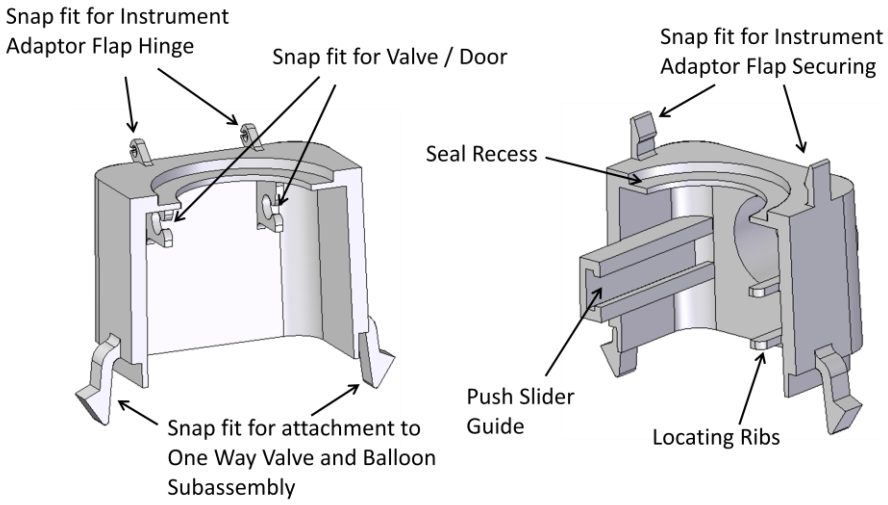


Figure 12: Upper Housing Pieces

A push slider guide has been designed into Upper Housing 1 to align the slider for the push button. Locating ribs are designed into the part so that both housing pieces can easily slide together during assembly. A snap fit is designed on the top of Upper Housing 2 to act as a hinge for the Instrument Insertion Adapter Flap. Snaps are also designed in the top of Upper Housing 1 to hold this flap in place when an instrument is being inserted into the body cavity. Snaps are also in place to guide the Upper Housing into the valve Body Housing during assembly.

Desufflation Button Mechanism:

The Desufflation Button mechanism has not been redesigned significantly either. This mechanism was understood to function properly and is a simple design. The Push Button itself was modified to have a slightly larger diameter to compensate for the recess causing a little more difficulty in pressing the button. The Push Button will still have a Push Button Cover (part number 14 on the BOM) to prevent leakage in the space between the button and the hole in Upper Housing 1.

The Valve / Door will be attached to Upper Housing 2 by a snap fit into the designed snaps. A spring (part number 12) will be attached here to provide the valve door with a resting position at the top roof of the Upper Housing, pressed snuggly to the seal. The full assembled mechanism, excluding the spring, in its resting position in Figure 13.

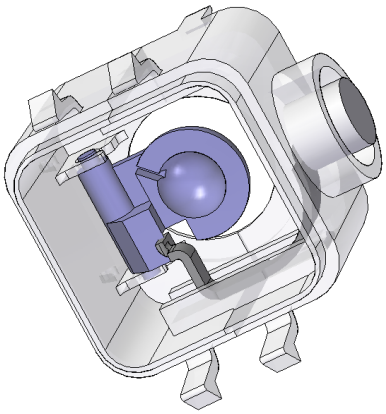
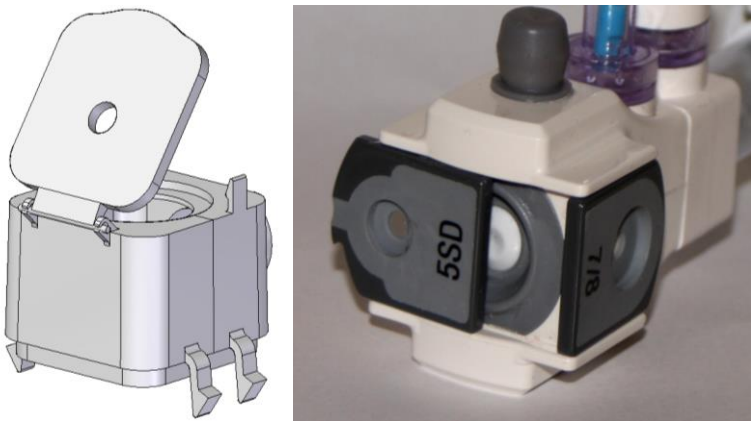


Figure 13: Desufflation Button Mechanism

Instrument Adapter Flap:

The Purpose of the Instrument Adapter Flap is to create a sealing surface around any tool of varying diameters so that no gas will leak from the body cavity when an instrument is inserted and the Valve / Door is compressed.

As compared with the original design, the Instrument Insertion Adapter Flap has been reduced from two flaps to one flap in the redesign. This was done based on the observation that the small rubber hole on the original designed adapter flap 5SD and 7/8 (shown in Figure 14) was approximately the same size, only the outer hole diameter varied significantly in size. So, it was assumed that a universal, one-size-fits-all adapter flap can be used in place of these two flaps by potentially using a different, more flexible rubber and having the outer diameter large enough for the varying range of instrument sizes to be inserted. This detail is not shown in the model in Figure 14. If, however, a tool of diameter approximately equal to 10 mm is being inserted into the body cavity, it can be inserted directly through the seal and Valve / Door without the use of the adapter flap, while still not causing significant gas leakage from the body cavity.



(a) (b)

Figure 14: Instrument Insertion Adapter Flap: (a) new design (b) original design

The slider mechanism for positioning the adapter flaps was also replaced by a hinge mechanism. This change was made because of the slight degree of difficulty for moving the adapter flaps in place, directly concentric with the cannula. The hinge design is easy to use and positions the flap more accurately than the slider design.

Manufacturing and Material Processing

There are four main components previously discussed that will be significantly modified in this redesign. The manufacturing and material processes might need to be adjusted for these components. These adjustments are discussed below.

Outer Tube/Valve Housing:

The outer tube will be made from the same material as it is now (which we think is some sort of polycarbonate ABS plastic). It will be formed by an injection molding process. The basic cross section of the mold is shown in Figure 15.

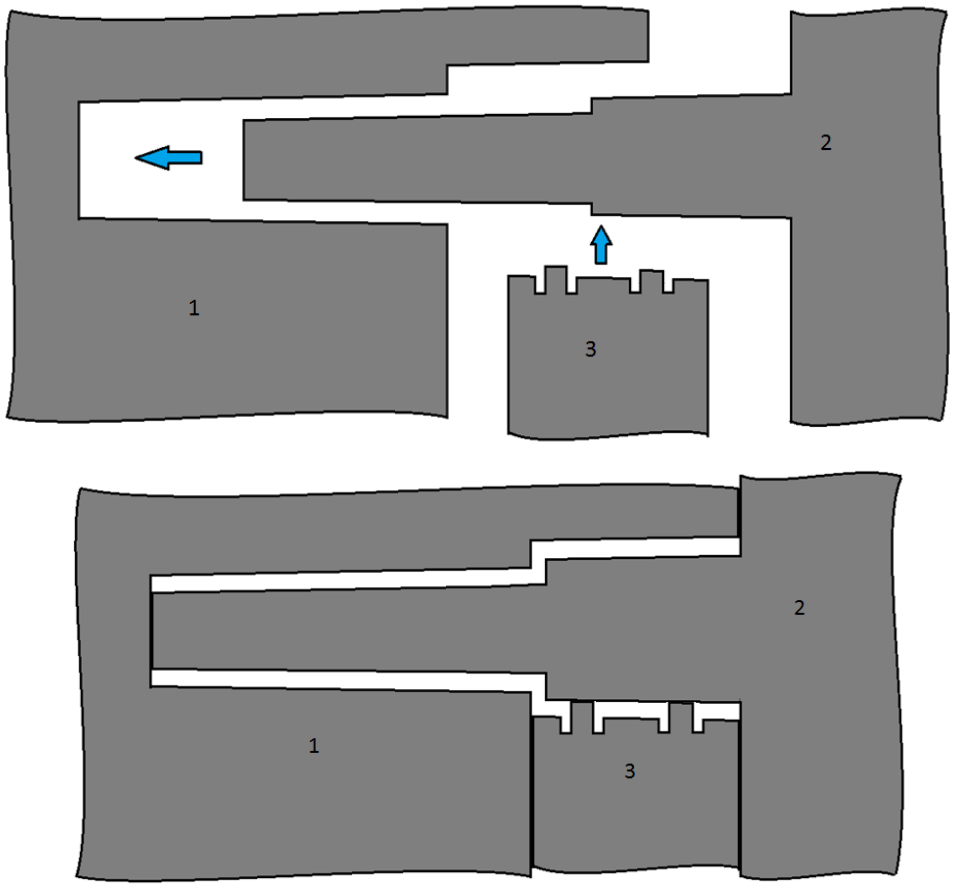


Figure 15: External Tube Mold Cross Section Design

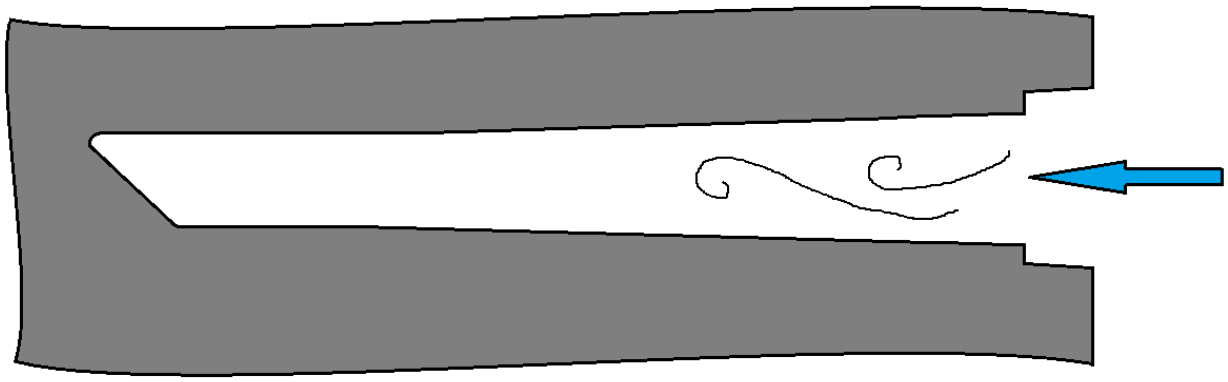
This diagram shows that there will be three main components to the mold, one which creates the majority of the outer surface, one which creates the inner surface, and one which details the geometry for the inflation ports. Injection ports are not shown. Notice that the tube geometry has a slight draft angle designed which will allow for easy release from the mold surface.

The plastic injection molding process will likely be outsourced to an injection molding facility who is readily equipped to do such molding. This process is estimated to cost a little more per part (compared to the original valve housing) because of the extra material to construct the outer tube. It also will have an additional cost at the beginning to construct a new mold. This cost is justified by the fact that the number of parts is being significantly decreased to reduce assembly time and labor costs and also this means other part formation processes can be eliminated.

Because of the requirements of the molding process, there will need to be a small draft angle included on the External Tube. This will cause the overall outer diameter to be slightly larger than that of the existing design. For this design, a draft angle of 1^{o} was considered.

Internal Tube:

The inner tube will be made from the same material as the tubes are currently. This part will be formed in a blow molding process, where the basic molding shape is shown below.



Following the creation of the basic shape through the blow molding process, the end of the tube will be pierced by a punch to create the hole in the bottom of the tube that is used for inflation of the body cavity and instrument insertion. Also, the thin membrane will be attached to the tube, either by the same process that is used for the flexible rubber on the adapter flaps, or it will be stretched and sutured like the Balloon.

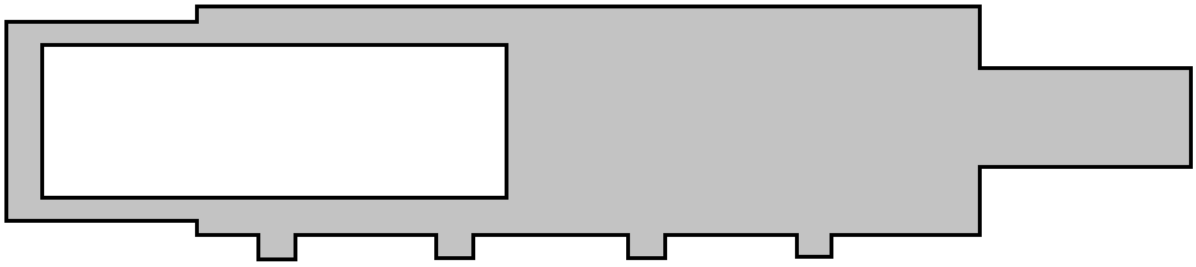
The geometry for this new inner tube design is a little more complex than that of the old inner tube design. This will result in a small increase in cost for this part as well. Also, there will be an added cost since a new mold will need to be created again. But, once again, parts are being eliminated because of this design, so the assembly cost will be decreased and other part formation processes are once again eliminated.

Upper Housing:

The upper housing parts will be modified slightly, but will still be injection molded in the same process that it used currently. They will be made from the same material in use now, and will have approximately the same material volume.

Collar/Latch:

The new collar design will be made from one piece of formed sheet metal, probably steel because it is more resistant to fatigue than other metals such as Aluminum. The initial shape will be of the basic form shown below:



It will then be folded to create the basic flexible collar/clasp shape necessary for locking the mechanism. The manufacturing of this component might also be outsourced to another company more familiar with making these types of clasps (for example ….). In this way, the clasp could be designed to function within its endurance limit so that no fatigue failure would be likely to occur when the latch is used within its desired bending range. Using an outside source for manufacturing of this component would benefit the design based on this source's expertise for designing similar devices and the availability of resources.

This part could potentially be purchased premade. However, the benefit of custom designing this part is that the flaps on the bottom can be created as a surface for easy attachment to the sponge. Also, due to the small draft angle on the external tube, the part is somewhat conical. This clasp may need to be designed such that is bent in somewhat of a conical configuration with a slope angle matching the draft angle. This would reduce pressure concentrations by distributing the load from the clasp on the tube.

Design for Assembly (DFA) Analysis

A design for assembly analysis was done on both the original design and the redesign to compare the two products. The original design DFA was used to help guide design changes during the redesign process.

Original Design DFA:

Figure 16: Assembled Insufflator, Original Design

To begin the assembly analysis, the disassembly sequence was determined from the manufacturer, although, detail drawings were not provided. It was found that there are a total of 32 components with 3 subassemblies. The high-level disassembly process is shown in Figure 17 and Figure 18.

Next, a formal DFA analysis was performed to determine the assembly index and number of parts required (the DFA analysis is contained in the Appendix). The assembly index was calculated to be 188. Evaluation of the assembly suggests that only 12 parts are required giving a part reduction index of 0.625 (ideal = 0).

Based on this analysis, the focus of the redesign was to modify the Collar and Internal/ External Tube areas due to reliability issues with the clamp (i.e. breaking) and gas leakage between the inner and outer tube and between the outer tube and the valve assembly. In addition to increasing the reliability, parts were redesigned to provide improved assembly (top-down) and overall assembly index and part reduction. The key areas of focus were (1) combining the upper housing and external tube housing, (2) combining the Internal Tube and Obturator, (3) eliminating blunt tip and handle subassembly, (4) redesigning the collar, and (5) redesigning the instrument adaptor flap.

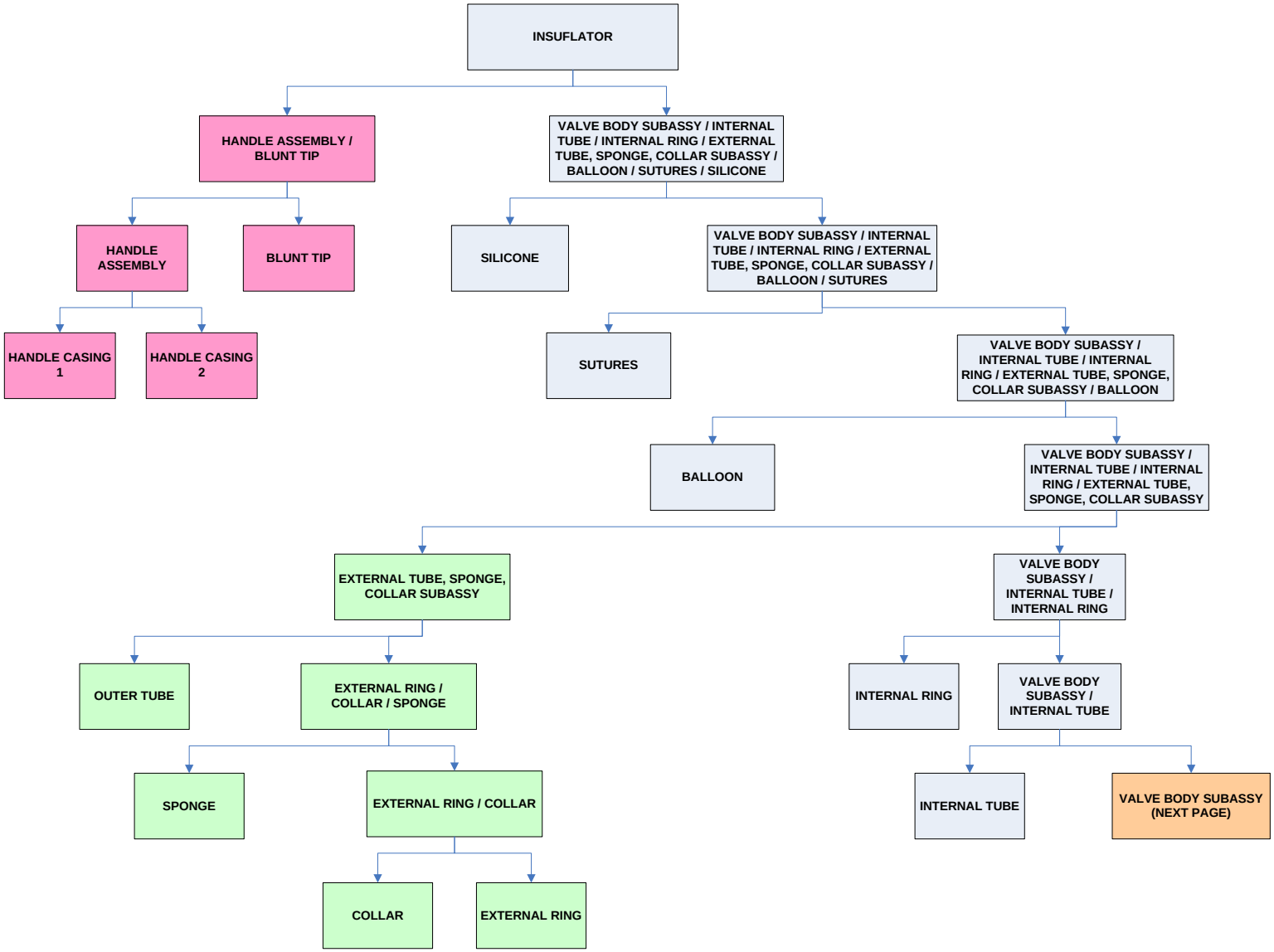


Figure 17: Assembly Sequence

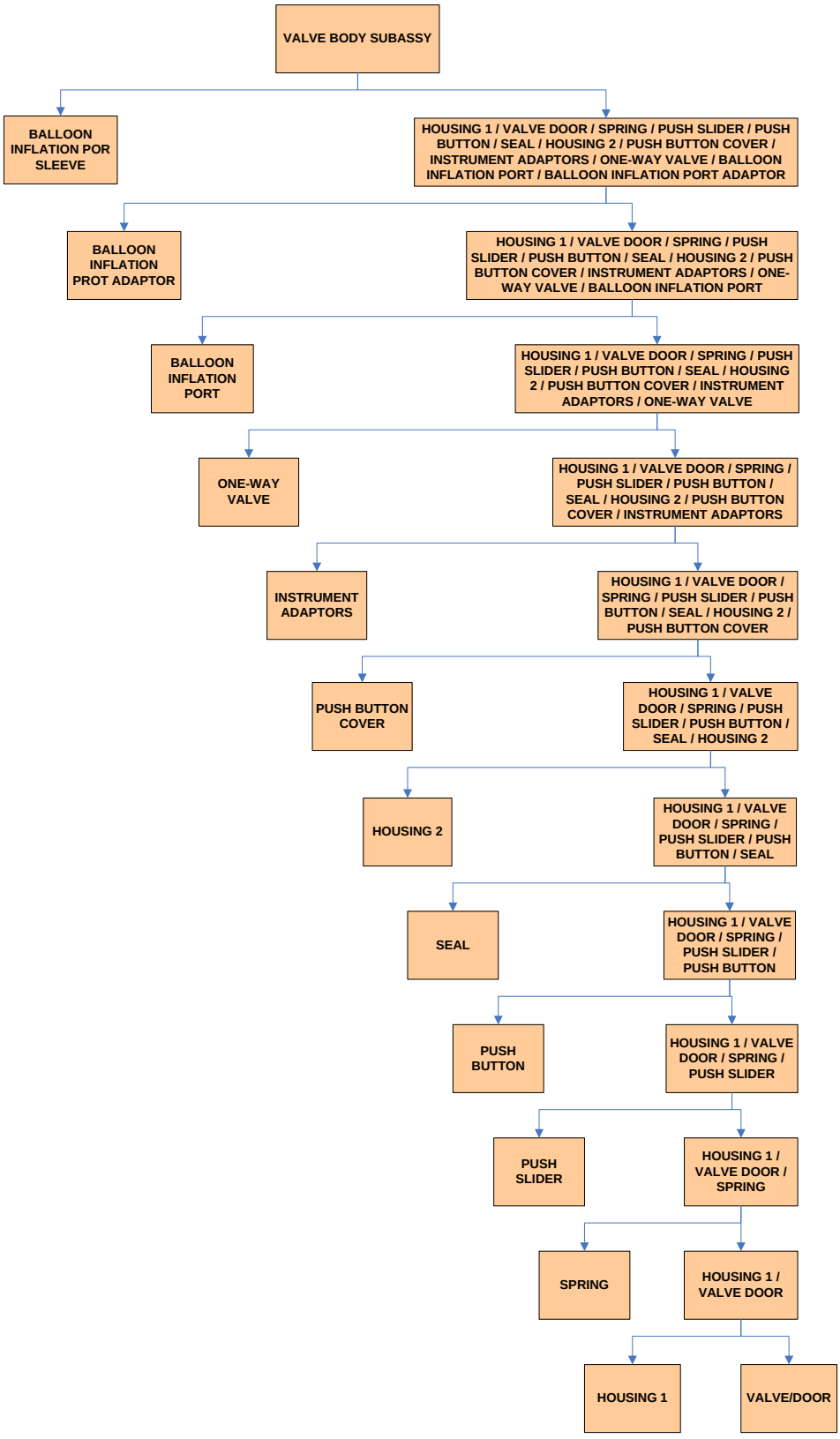


Figure 18: Valve Body Subassembly Sequence

Redesign DFA:

For the redesign, there are a total of 20 components with 3 subassemblies: Upper Housing Subassembly, One-way Valve/External Tube Subassembly, and Sponge Collar Assembly. First each subassembly will be explained followed by the final assembly sequence.

Upper Housing Subassembly:

The upper housing subassembly is assembled first and consists of nine (9) components as shown in Figure 19. The assembly sequence and method is detailed in Table 2.

Table 2: Upper Housing Subassembly Sequence

Part Number and Description	Assembly Method
1. Upper Housing 2	Base of the subassembly
2. Valve/Door	Snaps top-down into the Upper Housing 2. Valve/Door is required to be held in place for the next assembly step
3. Spring (not shown in figure)	Spring connected to Upper Housing 2 and Valve/Door. Similarly, the Spring must be held in place for the next assembly step.
4. Push Slider	Push Slider is recessed into the Valve/Door. The Push Slider must be held in place for the next assembly step. Tension must is applied to spring.
5. Push Button	Push Button snaps into Push Slider. The Push Button must be held in place for the next assembly step. Tension must be applied to spring.
6. Seal (not shown in figure)	Seal is placed between the Valve/Door and Upper Housing 2. Once in place, the subassembly is not required to be held in place.
7. Upper Housing 1	The Upper Housing 1 slides and snaps into Upper Housing 2.
8. Push Button Cover (not shown in figure)	Push Button Cover is attached to Push Button
9. Instrument Adaptor Flap	Assembly is rotated 90°. Instrument Adaptor is snapped into Upper Housing 2. This completes the subassembly

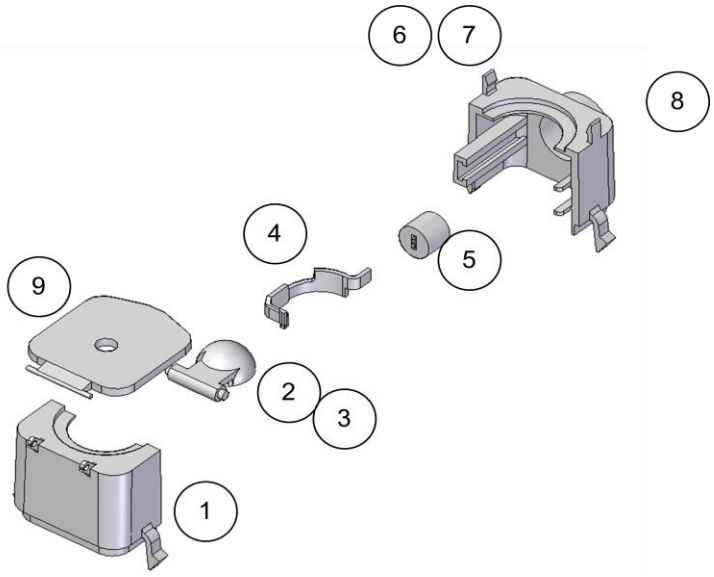


Figure 19: Upper Housing Subassembly

One-way Valve / External Tube Subassembly:

The one-way valve and external tube assembly consists of five (5) components as shown in Figure 20. The assembly sequence and method is detailed in Table 3.

Table 3: One-Way Valve / External Tube Subassembly Sequence

Part Number and Description	**Assembly Method**
1. Valve Body Housing / External Tube	Base of the subassembly
2. Inner Tube	Snaps top-down into the Valve Body Housing / External Tube. This has a locational interference fit to prevent leakage between the two tubes.
3. One-way Valve	Assembly rotated 90°. One-way valve snaps into Valve Body Housing / External Tube.
4. Balloon Inflation Port	Balloon Inflation Port snaps top-down into Valve Body Housing / External Tube.
5. Push Inflation Port Sleeve	Balloon Inflation Port Sleeve snaps top-down into Valve Balloon Inflation Port. This completes the subassembly

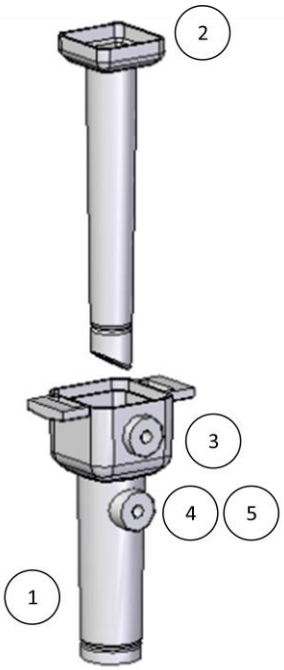


Figure 20: One-Way Valve / External Tube Subassembly

Sponge / Collar Assembly:

The final subassembly consists of two (2) components as shown in Figure 21. The assembly sequence and method is detailed in Table 4.

Table 4: Sponge / Collar Subassembly Sequence

Part Number and Description	Assembly Method
1. Sponge	Base of the subassembly
2. Collar / Clasp	Attached top-down to the sponge with glue

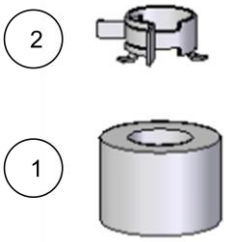


Figure 21: Sponge / Collar Subassembly

Final Assembly:

The final assembly consists of the 3 subassemblies in addition to the assembly of the inflation balloon as shown in Figure 22. The assembly sequence and method is detailed in Table 5.

Table 5: One-Way Valve / External Tube Subassembly Sequence

Part Number and Description	Assembly Method
1. Upper Housing Subassembly	Base of the final assembly
2. One-way Valve and External Tube Subassembly	Snaps top-down into the Upper Housing Subassembly.
3. Sponge / Collar Subassembly	Assembly rotated 180°. Slides over External Tube and is held in place by the Collar / Clasp.
4. Balloon	Balloon is slides over External Tube top-down. Balloon must be held in place until sutures are attached.
5. Sutures	Sutures slide over the Balloon and engage into grooves in the External Tube, holding the Balloon in place.
6. Silicone	An application of Silicone is applied over the balloon and Sutures to secure it in place and to proved a protective coating to the patient.

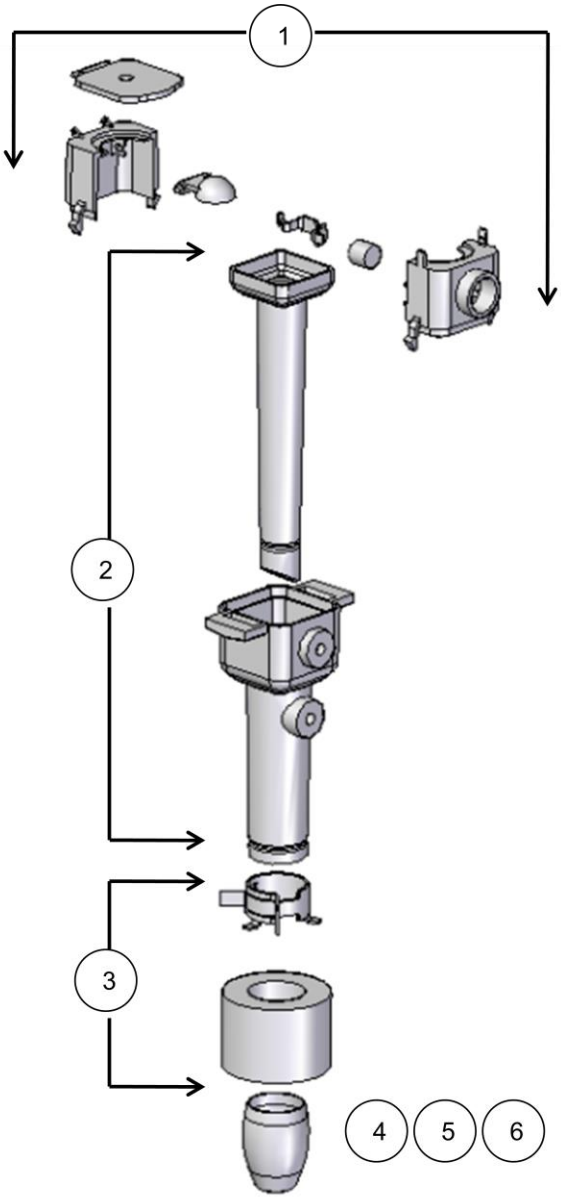


Figure 22: Complete Assembly

The proposed redesign was successful in reducing the number of parts from 32 to 20 (38%) and the assembly index from 188 to 138 (29%). The keys changes to the success of the design were (1) combining the upper housing and external tube housing, (2) combining the Internal Tube and Obturator, (3) eliminating the blunt tip and handle subassembly, (4) redesigning the collar, and (5) redesigning the instrument adaptor flap.

Although significant strides were taken to reduce the number of parts, the DFA analysis still shows eight unnecessary parts exist in the assembly process; therefore, further optimization of the assembly may occur in the future. However, the proposed modifications to the design can be implemented quickly, whereas, further modifications would require additional design time and would likely result in more complicated components increasing cost. Also, reducing the amount of parts even

further may make certain features of the design harder for the surgeon to use or more complicated to manufacture. The proposed design provides immediate benefits of increased reliability from the new collar design and elimination of leaking gas between the Internal Tube, External Tube, and valve assemblies, while minimizing the number of parts.

Note: The DFA analysis for the original and proposed designs may be found in the Appendix

Failure Modes and Effects Analysis (FMEA)

Design Failure Modes and Effects Analysis was done for all the components, within subassemblies, for both the old and new design. The FMEA along with the HOQ and the DFA was particularly helpful in directing us towards a new direction. We knew from Isbel and the reports from the markets that leakage issues from Cannula and the valves and breakage issues for the latch were some of the biggest concerns. The latch failure was also the most frequently and easily observable failure mode. Some of the failure modes relating the Cannula and the Obturator had to do with their shape. The Cannula and the Obturator being slender beams in shape were most prone to bending and buckling type of failures. The other most important failures were concerned with the perforation of the balloon as reported by surgeons to the company. This is one of the severe modes of failure and is also easily detectable as due to deflation, the balloon will not be able to hold up against the tissue and the insufflator might come out during surgery. The valves and insufflations ports were also given relatively high RPN numbers. This was because the failure mode associated with these parts i.e. leakage, though not as severe to the patient, directly negated the function of the whole product. With leakage, it is always difficult to find out the exact part where the leakage might be taking place and hence for all parts with leakage as a failure mode, the detectability was given to be high.

For our new design, the FMEA is done only on the parts that were redesigned or for new parts that were added. The Cannula is now made up of the inner tube which has been shaped into a conical ended part and hence replacing the Obturator and the outer tube which has been made a part of the lower housing and is made of the same material as the housings are. This has made the Cannula relatively stronger, as demonstrated again further ahead in the strength analysis, thus reducing the possible occurrence of the breakage due to bending and/or buckling. Furthermore, the inner tube now comes down and rests on the shoulder and is stuck to the outer tube using glue which acts as a seal preventing leakage. All these modifications thus reduced the overall RPN for the new Cannula i.e. the outer tube and inner tube to 108 (72 + 36) from 168 for the old design. The latch was also drastically redesigned by reducing the number of parts and making it out of metal which was inherently stronger than the older design. We believe that this takes care of the failure due to breaking and hence a lower RPN number. The latch might hurt the doctor but we can have the edges rounded off to prevent that and hence that was not considered in the failure mode especially since the function of the latch was to lock the sponge. The overall RPN for the latch was also reduced to 84 from 150 (144 + 6) for the old design. Thus the biggest numbers on the RPN from the old design were reduced by around 40-45%

except for the balloon which had to be kept the same due to surgical issues though there were ideas (as shown in the design concepts) to get rid of that as well. The instrument adapter flaps will be purchased from outside as before and hence was not included in the failure mode analysis.

The FMEA chart used for the analysis is included in the appendix.

Tolerance Analysis

A tolerance analysis was conducted for various connections in the redesigned device. The most critical dimensions where failures might occur due to interference or significant air gaps were decided to be (1) the fit between the Internal Tube and the External Tube and (2) the fit between the Upper Housing and the External Tube / Valve Body Housing.

Internal Tube and External Tube:

As shown in Figure 23, there are two failure modes: (1) No clearance between the trocar sleeves; (2) Positive clearance between the sealing connection (leakage).

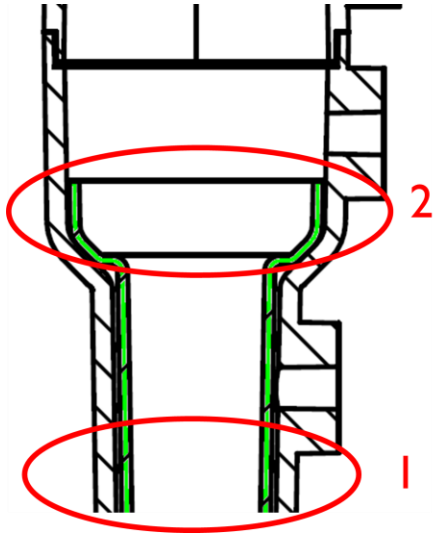


Figure 23: Failure Modes of the External Tube and Internal Tube

The possible tolerance of a thermoplastic or a thermoset is ±0.008 (0.2 mm) to ±0.002 (0.05 mm) inches (from http://en.wikipedia.org/). As it is a medical device, which should have a high quality, a tighter tolerance may be applied.

The function of the glue is not considered in this analysis. That is because the thickness of glue cannot be measured or taken into calculation as a dimension. The possibility that the glue fully seals a gap depends on the environment temperature, shape of the brush and the component, and handler's skill, which means to be unpredictable.

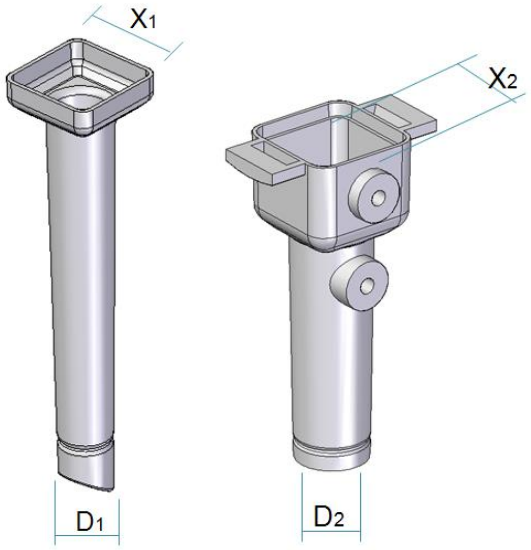


Figure 24: Dimensioned Variables for Tolerance Analysis

Failure mode 1:

The failure equation is

$$P_{(fail)} = D_2 - D_1 < 0$$

The original design has the outer diameter of the inner tube equal to 0.465 inches (D_1) and the inner diameter of the outer tube equal to 0.47 inches (D_2). Let us verify the possibility of failure of the original design if the tolerance is set to ±0.008 inches (0.2 mm).

$$P_{(fail)} = D_2 - D_1 < 0$$

$$\mu = D_2 - D_1 = 0.005$$

$$\sigma = \sqrt{(\frac{0.008}{3})^2 + (\frac{0.008}{3})^2} = 0.00377$$

$$P_{(fail)} = P_{(z<\frac{0-\mu}{\sigma})} = 9.25\%\ (old\ design)$$

The possibility of failure is 9.25%, which is not acceptable. So the clearance must be increased or the tolerance must be tightened. The clearance could be easily adjusted, while the tolerance for Failure mode 1 and 2 should be the same.

Considering the tolerance for failure mode 2 is more critical, which lead to the leakage problem of the balloon, the clearance of Failure mode 1 will be based on the tolerance determined by Failure mode 2.

Failure mode 2

The failure equation is

$$P_{(fail)} = X_2 - X_1$$

To totally eliminate the leakage, a locational interference fit is applied without considering the work of glue sealant. Referring the machinery handbook, the locational interference fit for steel (diameter between 0.4 to 0.7 inches) is 0-0.8 (in thousandth inch). Considering the elastic modulus of plastic is normally less than 2 GPa, while of the steel is 200 GPa, the locational interference fit for plastic equal to 0 - 16 (in thousandth inch) could be acceptable, which is 0 – 0.4 mm.

So, the tolerance and clearance are selected, and the possibilities of failure are calculated following the same procedure shown in Failure mode 1. The results are shown in Table 6.

Table 6: Tolerance Analysis Results for Internal Tube and External Tube Connection

	Failure mode 1	Failure mode 2
Tolerance	±0.1 mm	±0.1 mm
Clearance	>0.2 mm	-0.2 mm
Possibility of failure	0	0

Upper Housing and One-way Valve/Outer Tube Housing:

The purpose of this statistical tolerance analysis is to evaluate the fit between the upper housing assembly and the one-way valve/outer tube housing. For this assembly, the upper housing will be considered as a subassembly and will be inserted into the one-way valve/outer tube housing. Figure 25 and Figure 26 show the upper housing and one-way valve/outer tube housing components.

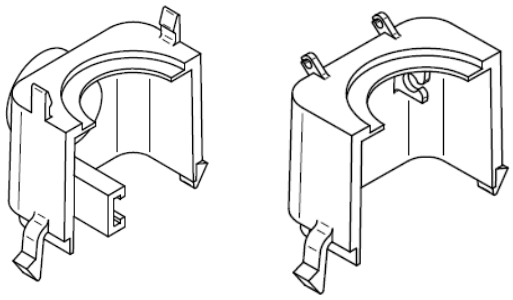


Figure 25: upper Housing 1 (left) and Upper Housing 2 (Right)

(will be assembled prior to insertion)

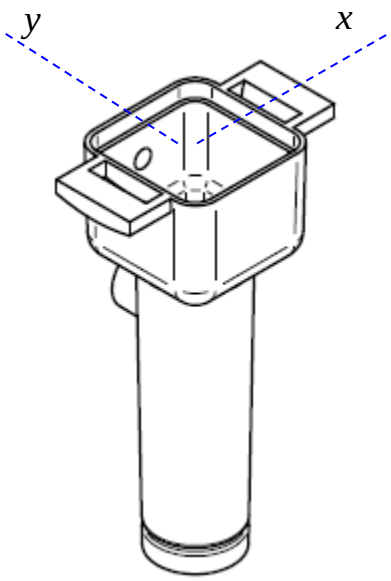


Figure 26: One-Way Valve/Outer Tube Housing

Similar to the previous analysis of the inner and outer tube assembly, the possible tolerance of a thermoplastic or a thermoset is ±0.008 (0.2 mm) to ±0.002 (0.05 mm) inches (from http://en.wikipedia.org/). The only failure mode considered during this analysis is not enough clearance between the two components. The two components will be glued once in place; therefore, the failure mode with too much clearance is not considered critical and will not be evaluated.

Failure Mode

To being the analysis, a tolerance of 0.2 mm was chosen because it is the least conservative; therefore, it would likely represent the most cost-effective design.

The failure mode equations for this assembly are as follows:

$$\text{(a) } P_{fail\_a} = x_V - x_{UP1} - x_{UP2} < 0$$

$$\text{(b) } P_{fail\_b} = y_V - y_{UP1} < 0$$

$$\text{(c) } P_{fail\_c} = y_V - y_{UP2} < 0$$

Where,

X and Y = direction as defined by Figure 26

V=one-way valve/outer tube assembly

UP1=upper housing 1

UP2=upper housing 2

The nominal (mean) and standard deviation values for this assembly are as follows:

Mean

(a) $\mu_a = \mu_{V\_x} - \mu_{UP1\_x} - \mu_{UP2\_x} = 27.88 - 13.70 - 13.70 = 0.48\,mm$

(b) $\mu_b = \mu_{V\_y} - \mu_{UP1\_y} = 27.88 - 27.40 = 0.48\,mm$

(c) $\mu_c = \mu_{V\_y} - \mu_{UP2\_y} = 27.88 - 27.40 = 0.48\,mm$

Standard Deviation

Note: The distribution of the dimensions for this evaluation are assumed to follow a normal distribution with a standard deviation of tolerance/3.

(a) $\sigma_a = \sqrt{(\frac{0.2}{3})^2 + (\frac{0.2}{3})^2 + (\frac{0.2}{3})^2}$ =0.115 mm

(b) $\sigma_b = \sqrt{(\frac{0.2}{3})^2 + (\frac{0.2}{3})^2}$ =0.094 mm

(c) $\sigma_c = \sqrt{(\frac{0.2}{3})^2 + (\frac{0.2}{3})^2}$ =0.094 mm

From the mean and standard deviations calculated above, the following probabilities of failure for each case are as follows:

(a) $P_{FAIL\_a} = P(z < \frac{0 - \mu_a}{\sigma_a}) = P(z < \frac{0 - 0.48}{0.115}) = P(z < -4.174) = 0.0015\%$

(b) $P_{FAIL\_b} = P(z < \frac{0 - \mu_b}{\sigma_b}) = P(z < \frac{0 - 0.48}{0.0.094}) = P(z < -5.106) = 0\%$

(c) $P_{FAIL\_c} = P_{FAIL\_b} = 0\%$

$P_{FAIL} \leq 0.0015\%$

Thus, the probability of failure in all three cases is equal to or less than 0.0015 %; therefore, a 0.2 mm tolerance would provide a sufficient and robust design. However, a 0.1 mm tolerance will be used to drive consistency across all dimensions of plastic components. From the previous analysis, a 0.1 mm tolerance was necessary for the inner tube and one-way valve / external tube to provide the

necessary clearances needed for balloon inflation and the appropriate fit at the sealing surface of the inner tube to prevent leaks.

Strength Analysis

Possible failures in original assembly:

1. Wrinkling, crushing and breaking of outer and inner tubes due to bending.
2. Collar/Link breaking due to bending stresses.
3. Balloon perforation.
4. Valves coming out due to back pressure.
5. Obturator breaking due to buckling/bending.
6. Separation of lower and upper housings in the valve body assembly due to poor glue joint.

Failure modes that can be controlled by us (since latch/valves are purchased): 1, 5, 6

Possible failures in new assembly:

1. Inner and/or outer tubes fail due to buckling/bending.
2. Plastic failure of metal latch due to extremely high closing force.
3. Balloon perforation.
4. Hinge for adapter flap breaks.
5. Valves come out due to back pressure.
6. Separation of lower and upper housings in the valve body assembly due to poor glue joint.

Failure modes that can be controlled by us (since latch/valves are purchased): 1, 4, 6

After careful manual inspection of the parts and since we have eliminated the Obturator/handle valve we believe that bending and buckling failure of the Cannula are the two most critical and possible modes of failures for the assembly.

Bending:

We can take the inner and outer tubes together to be one part as they shall bend as one part made of composite materials without relative slipping/shear. For bending we found experimentally that even a small amount of deflection leads to cracks being developed in the tubes for the old design. Let the critical deflection be δ for which the part cracks and at critical stress σ_{ult}. Let the bending moment applied by hand be M and hence we get the maximum induced stresses as,

$$\sigma_{max} = \frac{M.r_o}{I}$$

, where r_o is the outer radius of the outer tube and I is the moment of inertia given as,

$$I = \frac{1}{2}m(r_i^2 + r_o^2)$$

, where r_i is the inner radius of the inner tube and r_o is the outer radius of the outer tube.

For our new design, the moment of inertia increases as the inner and outer radii are both increasing and so is the mass. The mass will increase as the outer tube will be made of a heavier material.

Thus, for the same applied moment, M, the new maximum stress as compared to the old one is given as:

$$\frac{\sigma_{max,new}}{\sigma_{max,old}} = \frac{m_{old}}{m_{new}}\frac{r_{o,new}}{r_{o,old}}\left(\frac{r_{i,old}^2 + r_{o,old}^2}{r_{i,new}^2 + r_{o,new}^2}\right)$$

Now, $d_{i,old}$ = 10 mm, $d_{o,old}$ = 12.5 mm, $d_{i,new}$ = 10 mm, $d_{o,new}$ = 18.5 mm.

Hence,

$$\frac{\sigma_{max,new}}{\sigma_{max,old}} = 0.8576\frac{m_{old}}{m_{new}}$$

Moreover, our new tube has a density of 1.1 g/cc while the length is same as before i.e. 10 cm. The old tube has the same density. Thus the mass of the old cannula is, m_{old} = 4.86 g and of the new cannula is m_{old} = 20.92 g. This gives us an estimate of the ratio,

$$\frac{\sigma_{max,new}}{\sigma_{max,old}} = 0.1992$$

Hence the strength bearing capacity with respect to bending moment has increased by around 80%

Buckling:

For any bar to buckle, the critical load to be applied normally at the end is given as,

$$P_{cr} = \frac{\pi^2 EI}{L^2}$$

where E is the Young's modulus, I is the moment of inertia and L is the length of the bar.

Again, for our purposes, we assume inner and outer tubes together to be one part with effective stiffness modulus to be E. We know that the effective modulus of the new design is higher due to the stiffer material used for the outer tube. For us the total length, L, is the same. Hence the ratio of the new critical load to the old critical load is given as,

$$\frac{P_{cr,new}}{P_{cr,old}} = \frac{E_{new}I_{new}}{E_{old}I_{old}} = \frac{E_{new}}{E_{old}}\frac{m_{new}}{m_{old}}\left(\frac{r_{i,new}^2 + r_{o,new}^2}{r_{i,old}^2 + r_{o,old}^2}\right) = 1.72585 * \frac{E_{new}}{E_{old}} * \frac{m_{new}}{m_{old}} = 7.4290\frac{E_{new}}{E_{old}}$$

This clearly shows that the critical load to be applied for buckling to occur increases significantly only due to change in geometry and hence mass of the outer cannula.

Now, having compared the strength bearing capacity of the old and new cannulas, we go ahead and try to get the factors of safety for the two designs under same loading. We assume the original cannula was made of polyethylene terephthalate i.e. PET (used to make coke/pepsi bottles) with an average Young's modulus, E_{old} = 3 GPa and the ultimate tensile strength (since we observed the material to break as brittle material), $\sigma_{ult,old}$ = 30 MPa. For the molded parts assumed to be made of PC-ABS we have the average Young's modulus, E_{old} = 5 GPa and average ultimate tensile strength, $\sigma_{ult,old}$ = 60 MPa. These material properties were obtained from matweb.com

The assumed worse case load at the end of the cannula is taken to be around 10 kg-force, i.e. 100 N both, for bending and buckling which gives us the following induced maximum stresses,

$$\sigma_{max,old} = \frac{M.r_{o,old}}{I} = \frac{(100 * 0.1) * (0.625 * 0.01)}{\frac{1}{2}(4.86 * 0.001)[(0.5^2 + 0.625^2) * 0.01^2]} = 401485.5\ Pa$$

$$\sigma_{max,new} = \frac{M.r_{o,new}}{I} = \frac{(100 * 0.1) * (0.925 * 0.01)}{\frac{1}{2}(4.86 * 0.001)[(0.5^2 + 0.925^2) * 0.01^2]} = 344292.55\ Pa$$

Now, maximum allowed bending stresses are the flexural yield strengths as given previously. Thus the factor of safety, η, are given as

$$\eta_{old} = \frac{\sigma_{ult,old}}{\sigma_{max,old}} = \frac{30 * 10^6}{401485.5} = 75$$

$$\eta_{new} = \frac{\sigma_{ult,new}}{\sigma_{max,new}} = \frac{60 * 10^6}{344292.55} = 175$$

Thus, our above calculations, both qualitative and quantitative, show that the new design is much stronger than the current design as expected due to the modification of the outer tube. Thus the new design had not only helped in overcoming the critical design issues of leakage and part reduction but has also made the part stronger.

Cost Analysis

The biggest limitation for doing a cost analysis was that we did not have data on,

a) The cost of manufacturing incurred solely due to manufacturing processes
b) The total cost of making the Insufflator.

Hence, it was decided to calculate the cost saved per Insufflator which is one of the main aims of the redesign project. For performing this cost analysis, we looked at three aspects:

a) Cost saved due to overall material saved: This comes from the reduction in the number of parts. The molded parts for the handle valve assembly were assumed to be made of PC-ABS. The cost

of this material was found to be $0.20/kg from Dow Chemical's website. The density of the material was found to be 1.1g/cc. The material reduction came mostly from the reduction of handle valve assembly. The weight of the handle valve assembly was found to be 27 g. Now, we also added material to the part by making the outer tube of the same PC-ABS material. The volume of the increased part was found from CAD drawings to be 10.387447 cc and using the density the amount added was found to be 11.42619 g**.** Thus the net weight reduced (approximately) per Insufflator is 15.5738083 g. This gives a total cost saved to be around $0.00311476166 per Insufflator because of material reduction.

b) Cost saved due to labor time saved: This again comes from the reduction in parts as they results in an overall decrease in the assembly time. As estimation of the labor wage of $8.00/hour was made as per minimum wage standards. We disassembled the Insufflator and roughly tried to put in the assembly together similar to how someone in the factory would. This gave us an estimate of the time for each subassembly and the overall assembly. We then estimated the reduction in the assembly time for the new assembly (as shown in table below). The total estimated time saved was found to be 207.4 seconds per insufflator. Using the wage considerations, this gave us the labor cost saved per Insufflator to be around $0.4608889.

c) Purchasing cost saved: since the latch was being redesigned to be a much simpler and easily available part made out of steel we assumed, conservatively, that the purchasing cost per latch would cost atmost half as much as the old latch. The cost for the new latch was taken to be $0.10 based on the metal clips available in the market.

These calculations gave us a total cost saved per insufflator to be around $0.621614762. Now, the number of parts made per day in two shifts is 1600 (as provided by Isbel). Assuming the factory to be open 50 weeks a year, we obtained the total total number of parts made per year to be 560000. This gives us the total cost saved per year to be **$348104.30** per year. Refer to the cost analysis summary in Table 7. For a complete cost analysis break down, refer to the spreadsheet in the appendix.

Table 7: Cost Analysis Summary

Total time saved per insufflator (hours)	Total labour cost saved per insufflator ($)	Total Material cost saved per insufflator ($)	Total purchasing cost saved per insufflator ($)	Total cost saved per insufflator ($)	Total number of parts sold per year	Total cost saved ($)
0.057611111	0.460888889	0.003114762	0.1	**0.621614762**	560000	**348104.3**

Conclusion

As a result of the detailed analysis completed for the Insufflator device, a new device was designed with many improvements. A summary of the improvements is provided below:

- Reduction of the number of sealing joints and a change in the way the components are assembled reduces leakage.
- Reduction of the number of components and a change in the assembly procedure has increased the ease of assembly.
- Reduction in the number of components has simplified the use of the insufflator.
- Reduction of components and improvement in the collar design has reduced the chances of failure of the collar.
- Recessing the desufflation button has reduced the chances of accidental desufflation.
- Reduction in components and change in material has resulted in a cost reduction of approximately $350,000 per year.
- The change in geometry and material has increased the strength of the insufflator tube.

But, aside from this, there are also some disadvantages to the new design:

- Increase in the external tube diameter causes an increase in the size of the incision to be made on the patient's body (by a minimal amount).
- Change in geometry and in the placement of the insufflation ports results in a reduction in the range of collar/ sponge travel, reducing the range of insertion into the body cavity.
- Integration of components has made the flapper valve housing more complicated and would increase manufacturing costs.
- Change in the geometry of the outer tube results in a deep injection mold which would increase tooling and manufacturing costs.
- The membrane at the end of the inner tube might reduce flow rate of air into body cavity (Not significantly.
- The end of the Internal tube protrudes slightly further into the body cavity.

With all things considered, the advantages strongly outweigh the disadvantages. In fact, some of the disadvantages could be corrected for with potential iterations of the redesign. The outer diameter could be decreased by reducing the draft angle. The length of the tube could be extended to allow for more travel in the Sponge / Collar assembly. In regards to cost, the changes in geometry required for the molding equipment will not be as significant of a loss as the cost saved due to the other changes in the design. Overall, with a little more time and resources, the majority of these issues can be resolved, resulting in a clearly better design than the original.