Insufflator Redesign

Group 2

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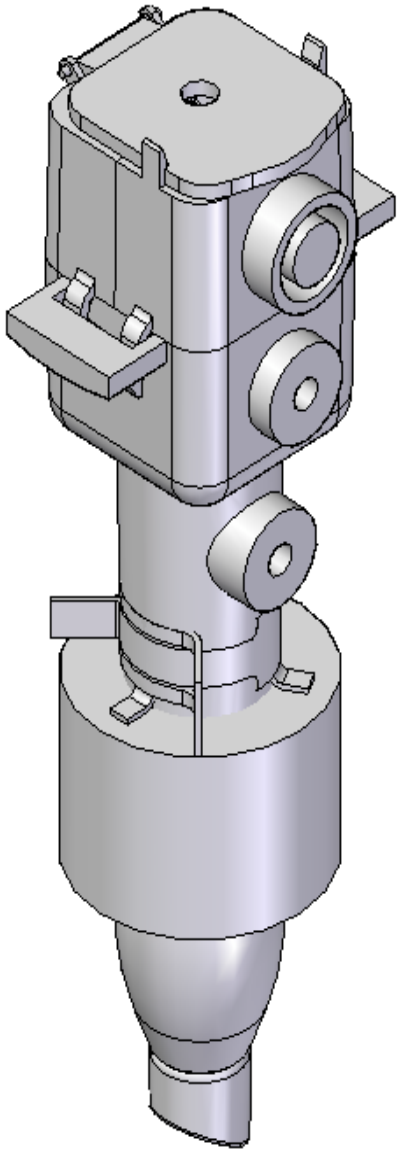
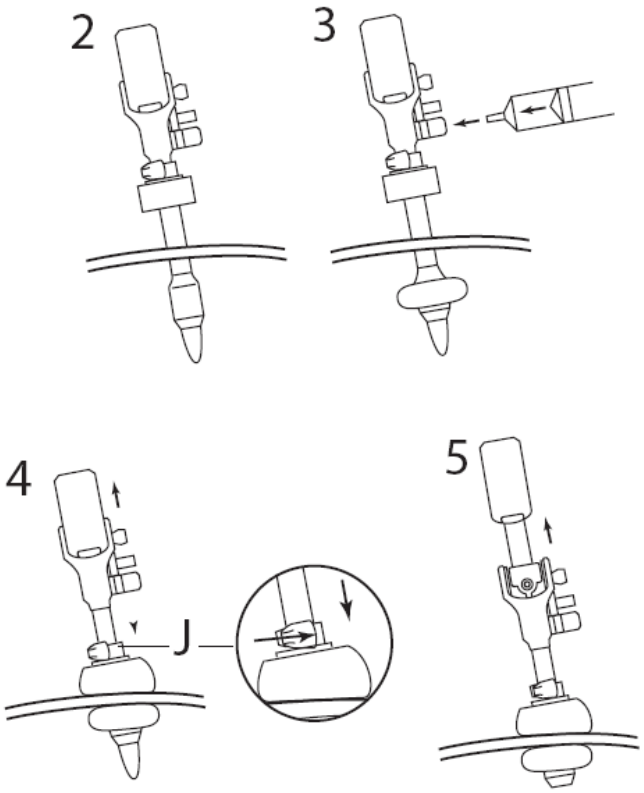


Background

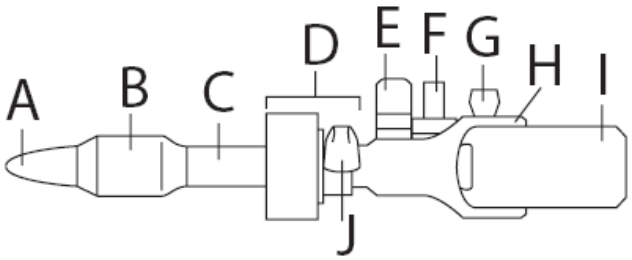
- This product is designed for laparoscopic surgeries. It has the following functions:
  - To create a channel through the abdominal wall, lock itself in the position and seal the incision.
  - To allow gas to pass into to insufflate the abdomen.
  - To allow gas to flow out to desufflate the abdomen.
  - To allow endoscopic instruments introduced and removed through the trocar sleeve.

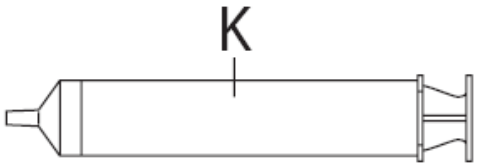
Instructions for Use

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.



Current Design





Number	Name	Function	Problem
A	BLUNT TIP	To push through the incision.	
B	BALLOON	To seal the incision from inside.	Might get 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 accidentally pressed.
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 push air into tube to inflate the balloon.	

HOQ Conclusions

The most important characteristics to be addressed turn out to be:

- Reduce leakage from insufflated body cavity
- Reduce leakage from insufflator joints
- Reduce the number of components

The roof of the house of quality provided the following insights:

- Reducing the number of components potentially reduces the chances of leakage
- Reducing leakage in the joints of the insufflator reduces the leakage of gases from the balloon volume as well as the body cavity

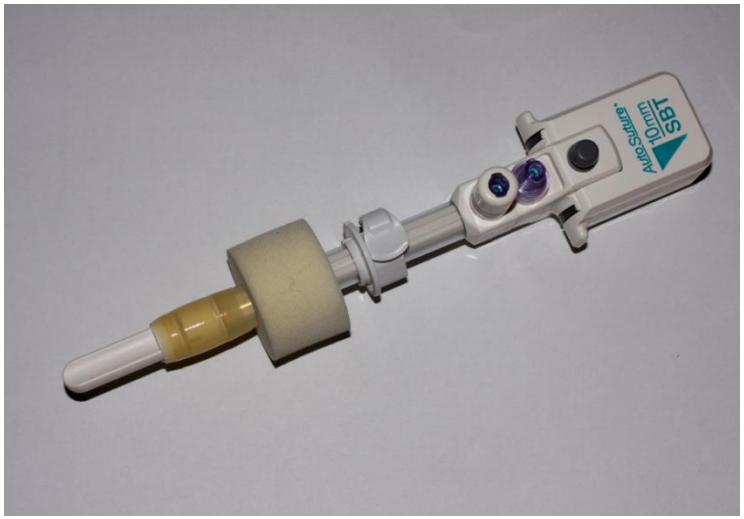
[Actual House of Quality is in backup slides]

FMEA: Old Design

Part	Function	Failure Mode	Effect	Cause	Corrective Action	Severity	Occurrence	Detection	RPN
Blunt Tip Trocar/Obturator	To push through the incision without causing pain	Does not push through the incision.	1. The insufflator does not go inside to the required depth; 2. Causes pain due to blunt tip during incision	1. Not enough pushing force, 2. Tip was manufactured too blunt	1. Push with right amount of Force; 2. Make the tip sharp	7	4	2	**56**
Cannula	1. To provide path for gas to the balloon 2. To provide path for gas to the abdomen 3. To hold the latch/collar/sponge assembly	1. Does not let air pass to the balloon and/or abdomen, 2. Does not hold latch/collar/sponge assembly	1. The balloon/abdomen fail to inflate, 2. The latch/collar/sponge assembly keeps slipping about the Cannula	1. Defective cannula (made such that there is no air gap between concentric tubes), 2. Leakage due to poor glue sealing/***breaks***, 3. Not made to spec for latch/sponge/collar inner diameter	1. Gap between the concentric tubes can be made generous; 2. Find ways of better sealing or use a single part for valve assembly	6	7	4	**168**
Collar	To provide support to the sponge	Does not provide support to the sponge	1. The insufflator slips completely into the abdomen; 2. The sponge gets squashed by the valve/handle assemblies	1. The collar materials fails and breaks apart.	1. Stronger material and/or part design	3	1	2	**6**
Latch	To lock the sponge/collar assembly in place	Does not lock	The sponge/collar assembly keeps slipping along the cannula and causes unstable operation	Breaks due to poor material or pins	1. New locking mechanism, 2. Stronger part design.	9	8	2	**144**

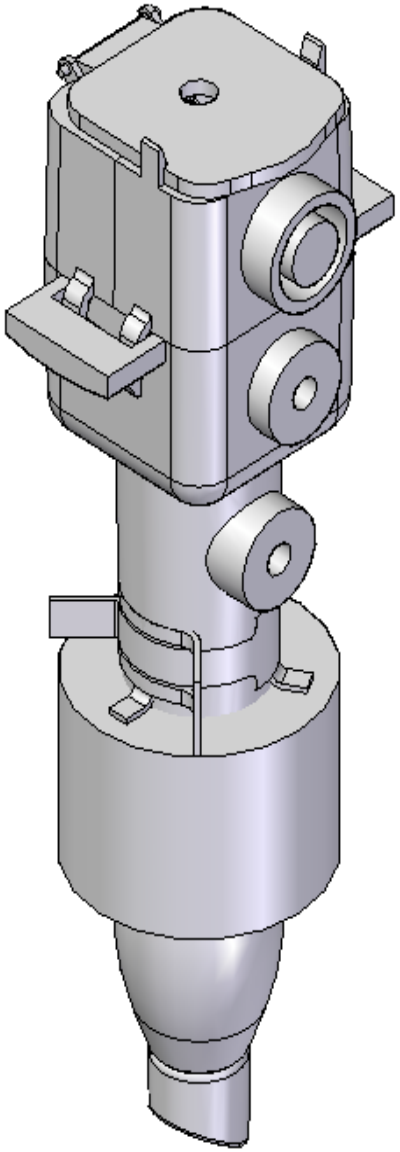
Redesign Concept

- Eliminates the need for an Obturator
- Combines the upper housing and external tube to reduce part count and leakage issues
- Includes new, easy-to-use collar / clasp
- One-size-fits-all instrument adapter flap.
- Recessed the Desufflation Button to prevent accidental deflation of body cavity



Old Design

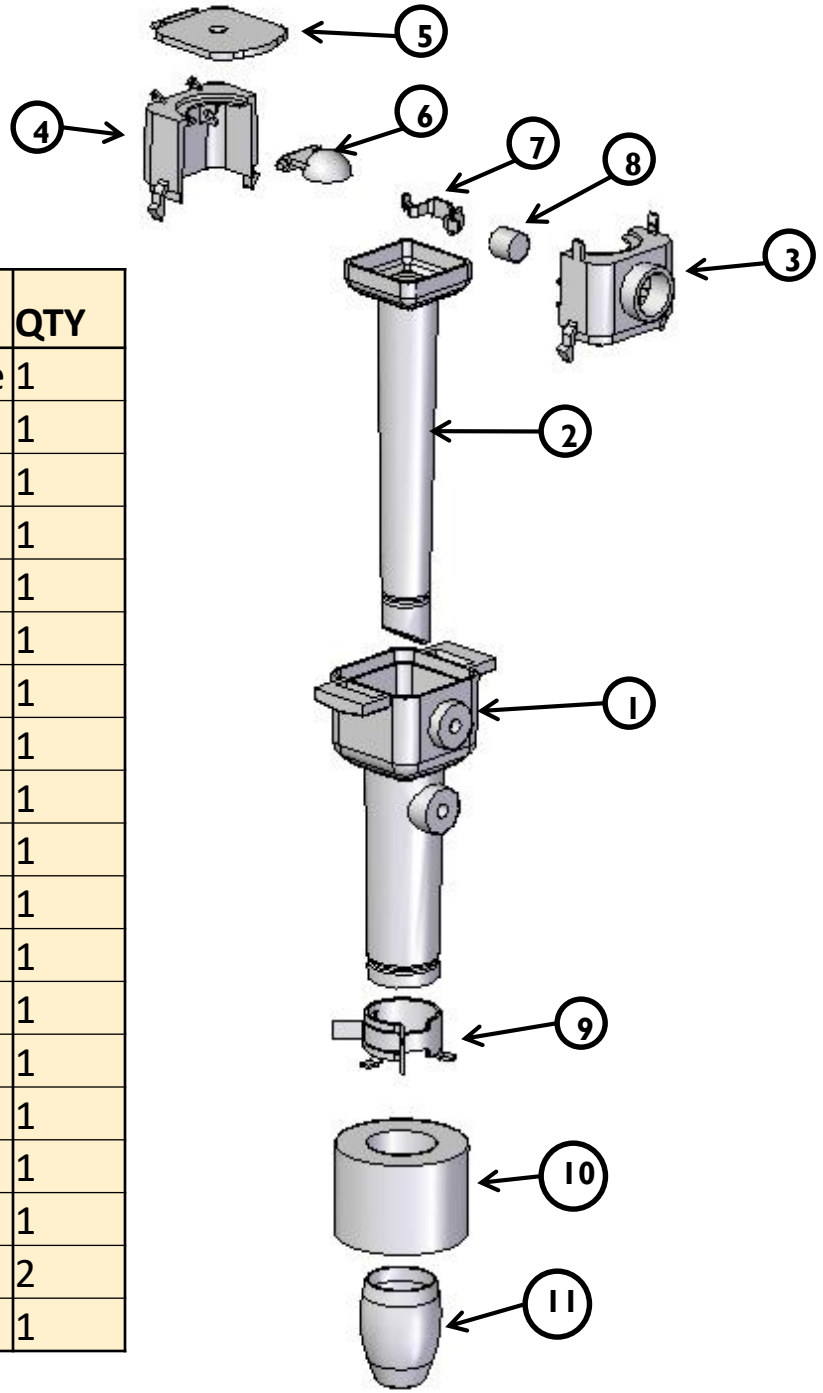
← VS →



New Design

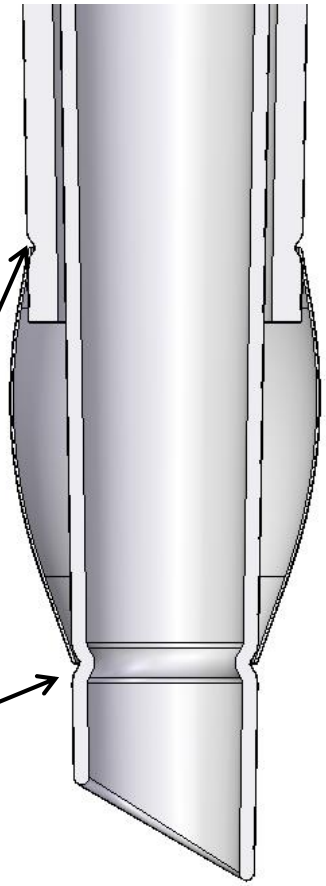
BOM

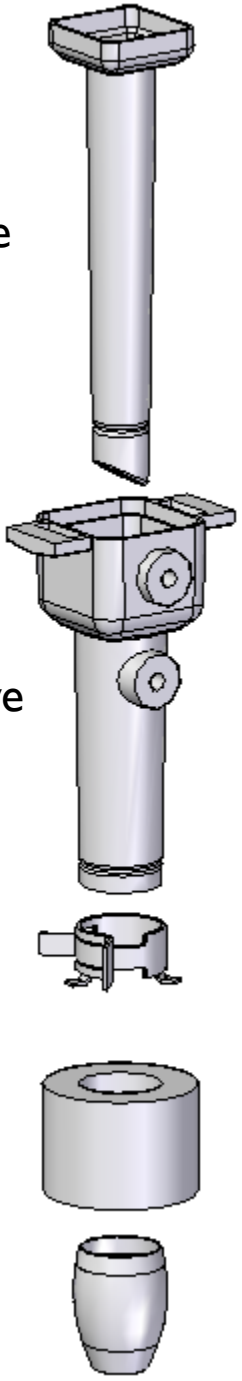
Part #	Description	QTY
1	Valve Body Housing / External Tube	1
2	Internal Tube	1
3	Upper Housing 1	1
4	Upper Housing 2	1
5	Instrument Adaptor Flap	1
6	Valve / Door	1
7	Push Slider	1
8	Push Button	1
9	Balloon	1
10	Sponge	1
11	Collar / Clasp	1
12	Spring	1
13	Seal	1
14	Push Button Cover	1
15	One-Way Valve	1
16	Balloon Inflation Port	1
17	Balloon Inflation Sleeve	1
18	Sutures	2
19	Silicone	1



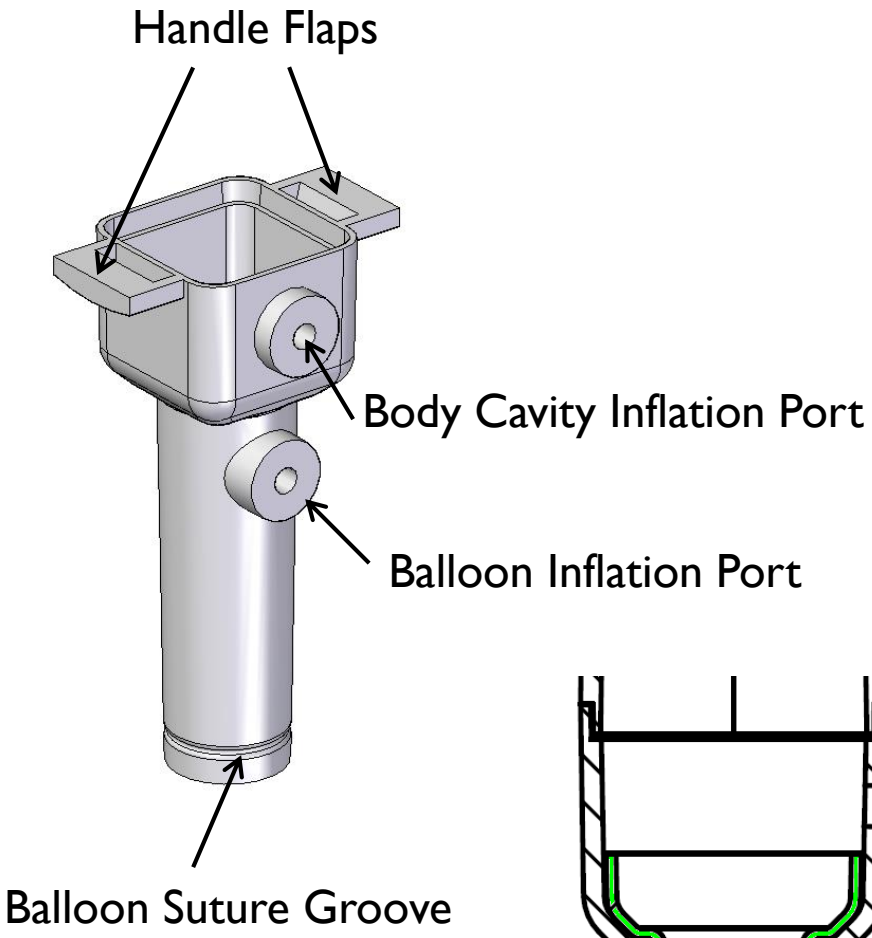
One Way Valve and Balloon Subassembly

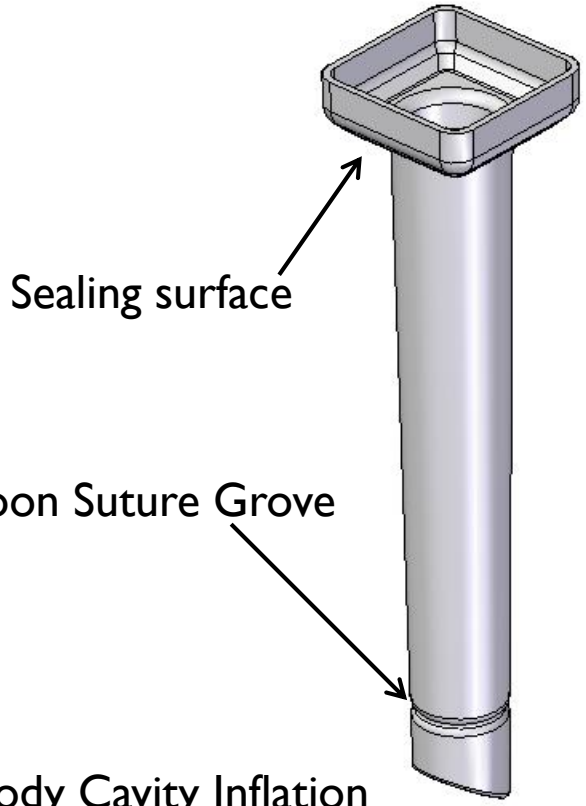
- Internal tube fits snuggly in external tube with small air gap for balloon inflation
- Clasp and sponge fit over external tube
- Balloon is sutured to external and internal tubes utilizing designed-in groove

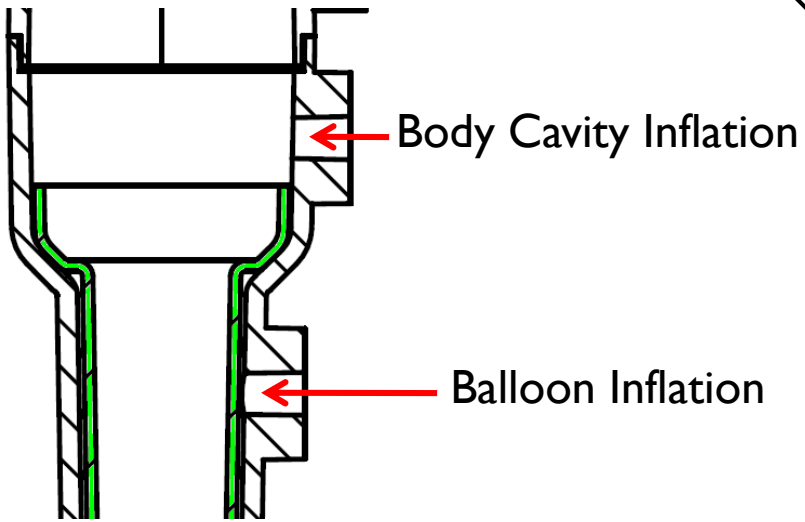




Internal and External Tubes



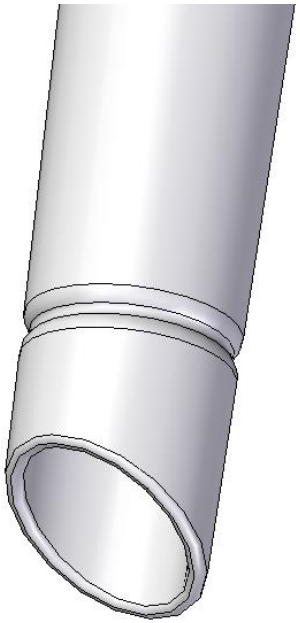


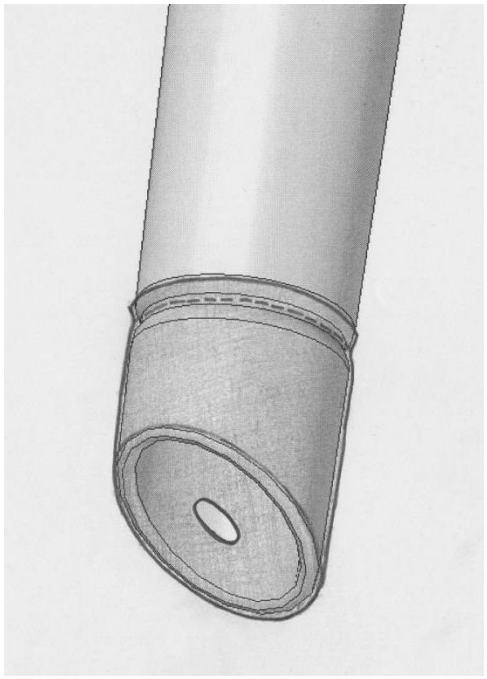


Internal Tube

- Slanted end for easy insertion into body cavity
  - Eliminates the need for an obturator

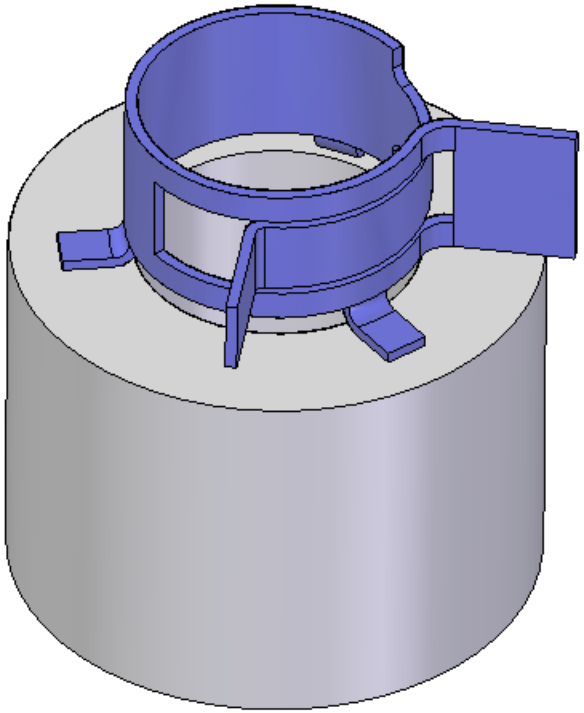
- Thin membrane covering to facilitate the easy insertion
  - Made from flexible material to allow instruments of all sizes to penetrate

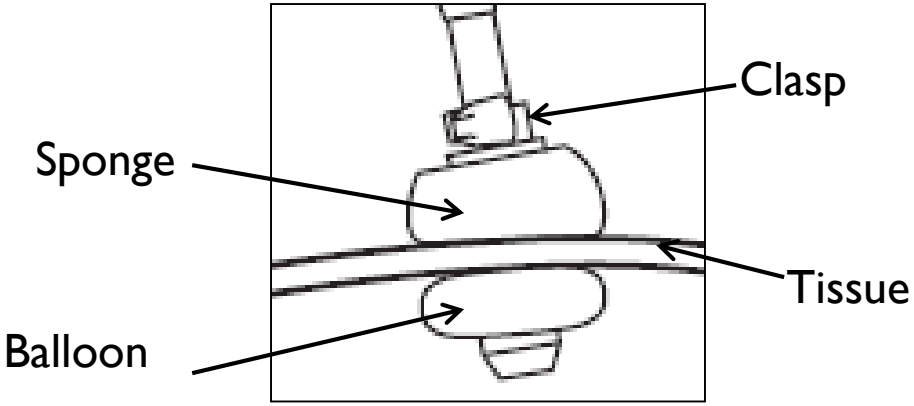




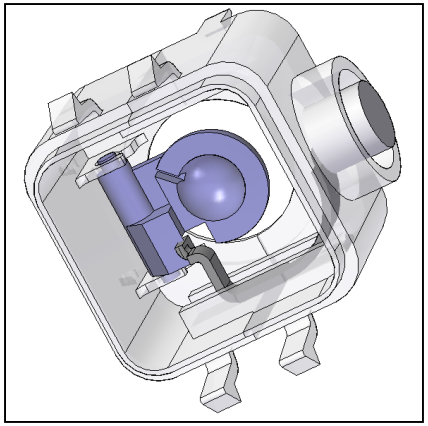
Clasp and Sponge

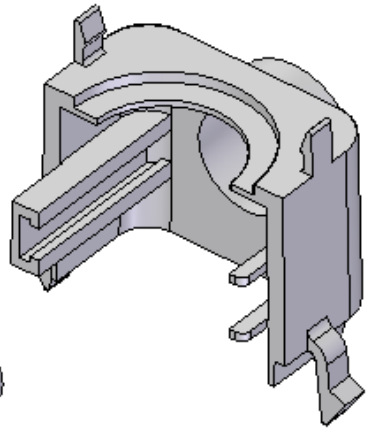
•Clasp redesigned to be made from one piece of material instead of 3 plastic injection molded pieces and 3 pins





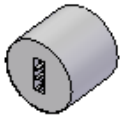
Upper Housing Subassembly



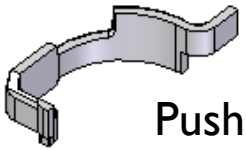


Upper Housing 1

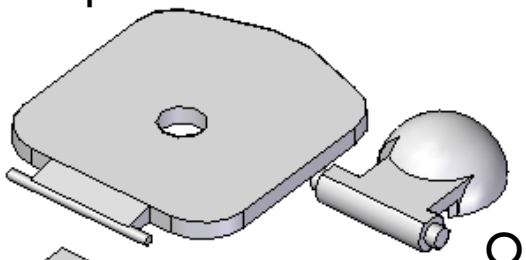
Push Button



Instrument Insertion Adapter Flap

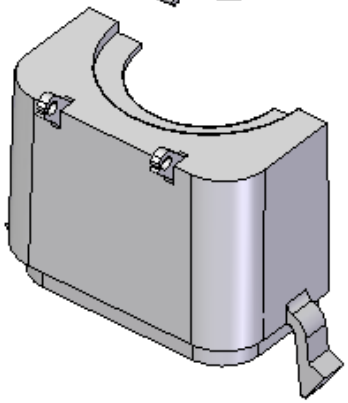


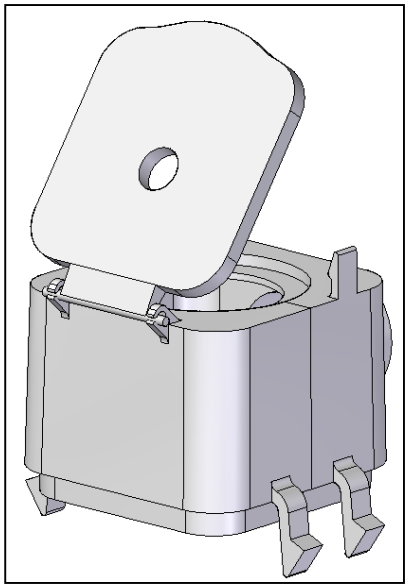
Push Slider



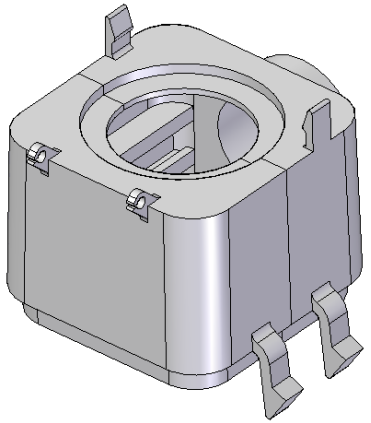
One Way Valve Door

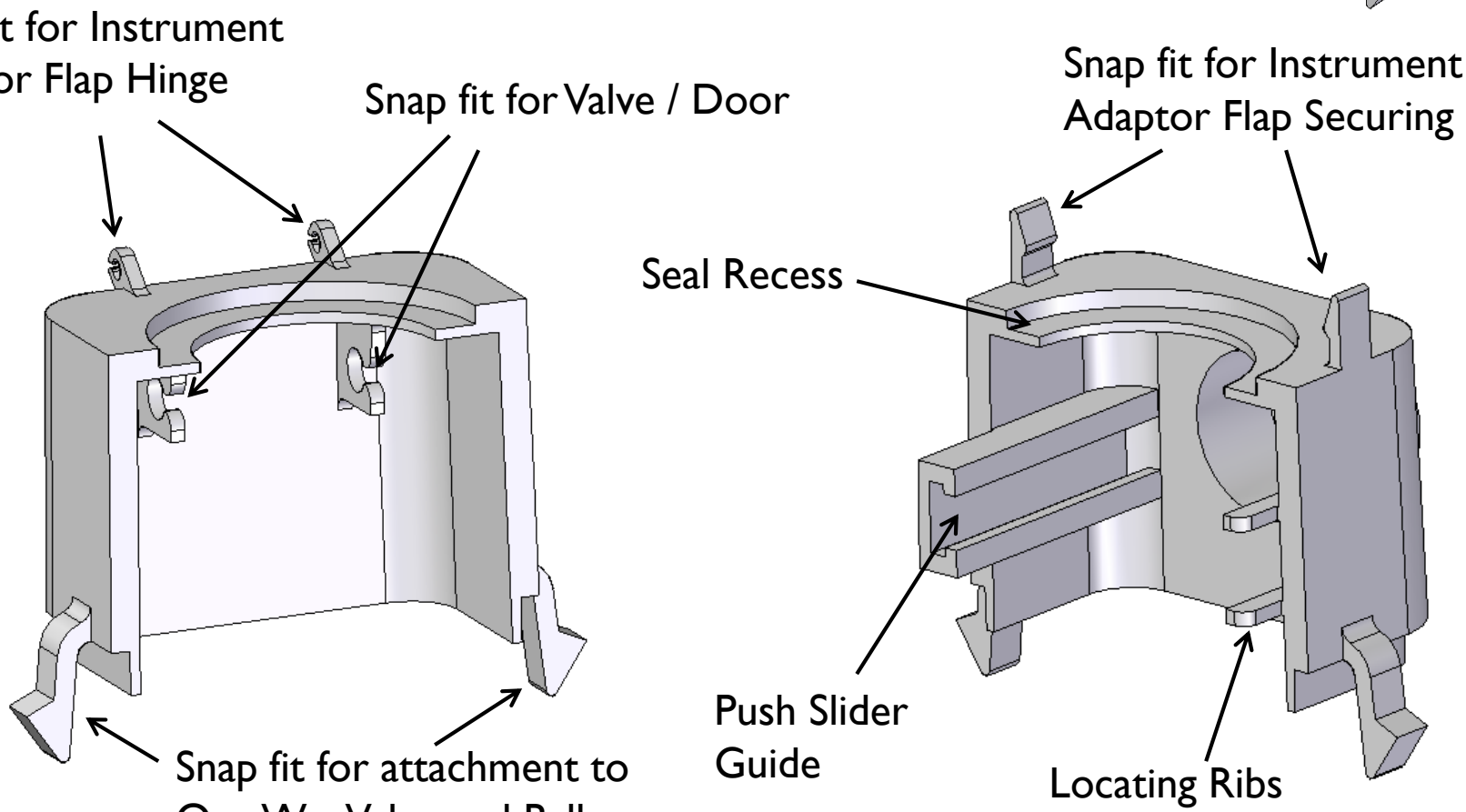
Upper Housing 2





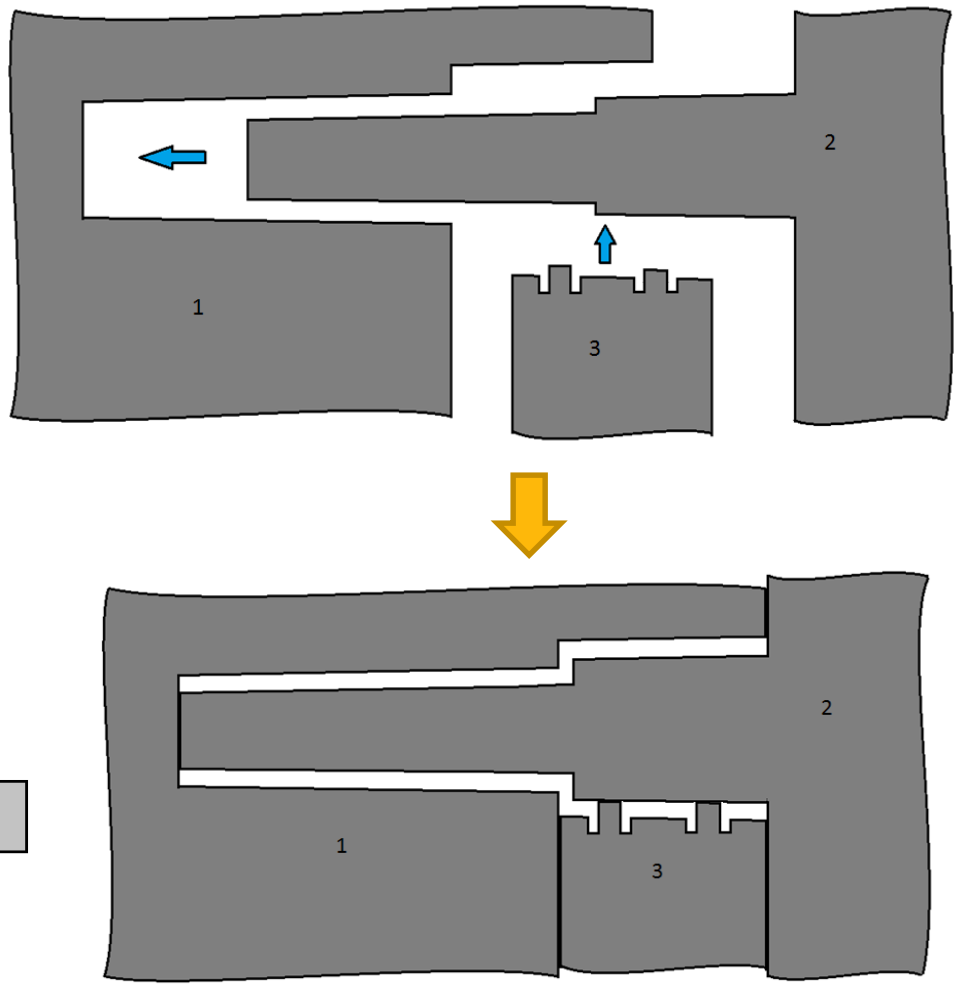
Upper Housing



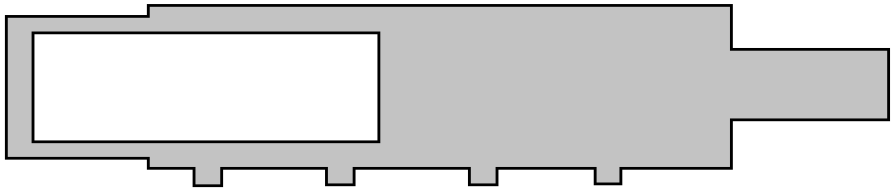


Manufacturing & Material Process

- Plastic Injection Molded
  - Outer Tube / Valve Body Housing
  - 2 Upper Housing Pieces
- Blow Molding
  - Inner Tube
- Sheet Metal Forming
  - Collar / Clasp



External Tube Mold Cross Section



Clasp Unfolded View

DFA Evaluation

- Original Design
  - Assembly Index = 188
  - Total Parts = 33
  - Total Req'd Parts = 12
  - Part Reduction Ratio = 0.6364
- Proposed Redesign
  - Assembly Index = 133
  - Total Parts = 20
  - Total Req'd Parts = 12
  - Part Reduction Ratio = 0.4000

Key Design Changes

- Combined upper housing and external tube
- Combined inner tube and the obturator
- Eliminated handle
- Redesigned collar (symmetric and 1/6th parts)
- Redesigned instrument adaptor

FMEA: New Design

Part	Function	Failure Mode	Effect	Cause	Corrective Action	Severity	Occurrence	Detection	RPN
Housing 2	To hold the spring/slider/external valve assembly and the adjuster flaps and also provide the recess for the desufflation button	1. The external valve assembly falls off, 2. The flaps do not get attached to the housing, 3. the recess does not prevent desufflation button from pushing in.	1. Leakage of air from abdomen, 2. Unable to install flap and let tools pass through. 3. The desufflation button still gets pushed in by mistake.	1. Improper tolerances/design/manufacturing defects, 2. Poor hinge connections, 3. Sudden/unwanted opening of the external valve.	1. Slot for slider should be proper fit with deep grooves, 2. Proper design/tolerances	4	5	2	**40**
Lower Housing + Outer Tube	1. To provide path for gas to the abdomen, 2. To provide attachment for the air/insufflation valves 3. To hold the latch/collar/sponge assembly,	1. Does not let air pass to the abdomen, 2. Does not hold the valves. 3. Does not hold latch/collar/sponge assembly	1. The balloon/abdomen fail to inflate, 2. The air leaks as valves are loose or come out, 3. The latch/collar/sponge assembly keeps slipping	1. Leakage due to poor air sealing/glue joint or broken tube due to poor strength, 2 and 3. Poor Design/manufacturing defects	Proper tolerancing, good design and choice of stronger materials	6	3	4	**72**
Inner Tube w/ Membrane	1. To provide path for gas to the balloon, 2. To act as an obturator, 3. To provide path for the tools	1. Does not let air pass to the balloon, 2. a) Does not push through the incision easily b) The backward force while pushing is bigger than what the glue joint can hold , 3. Does not let tools to pass through the inner tube.	1. The balloon fails to inflate, 2. Hurts the patient, 3. Camera/surgical tools are unable to get inside the abdomen.	1. a) No air gap/tolerance between the tubes, b) Broken tube, 2. a) Too blunt b) weak glue chemical and small contact surface between glue and inner, outer tubes, 3. The inner diameter less than 10 mm (or critical dia required)	1. good tolerances, 2. a) sharp right conical end, b) stronger glue, c) greater surface of contact area between glue and tubes	6	3	2	**36**
Latch/Collar	1. To provide support to the sponge, 2. To lock the sponge/collar assembly in place	1. Does not provide support to the sponge and does not lock itself at one place, 3.	1. The assembly keeps sliding up and down the cannula/outer tube, 2. Hurts patient/customer	1. The collar shears through the sponge; the collar is not dimensioned properly to hold on to the outer tube; the collar bends and weakens during closing	Specify these design requirements to the supplier.	7	6	2	**84**

Strength/Failure 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

Strength/Failure Analysis (Contd.)

- **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.
  - 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

Thus,

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

For us, $r_{i,old}$ = 10 mm, $r_{o,old}$ =12.5 mm, $r_{i,new}$ = 10 mm, $r_{o,new}$ = 18.5 mm

Thus,

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

Considering the new mass to be at least twice as much as old mass. Hence, we get:

$$\frac{\sigma_{max,new}}{\sigma_{max,old}} = 0.4288$$

The strength capacity with respect to bending moment has nearly doubled

Strength/Failure Analysis (Contd.)

- **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,

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

  - **This clearly shows that the critical load to be applied for buckling to occur increases significantly even without considering the increase in mass.**

Thus, our above calculations for bending and buckling show that the new design is much stronger than the current design even without considering the effect of increase in mass which is a material property (density).

Cost Savings Per Year

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**

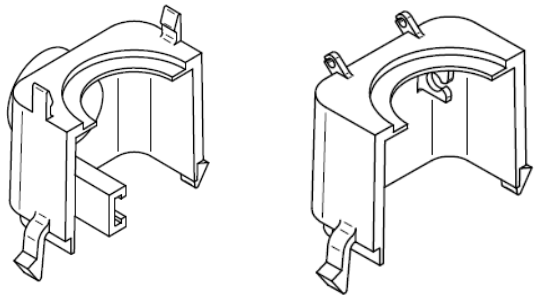
- Assumptions:
  - Material used for molded parts: PC-ABS costing $2e-4/g and having a density of 1.1g/cc
  - Labor cost: $8.00/hour
  - New Steel latch/collar costs half as much as old latch/collar i.e. $0.10/part
  - 2 shifts of 800 parts each day for 50 weeks a year.
- Calculations:
  - Weight of handle assembly (grams) = 27 g
  - Increased volume of the outer tube made out of PC-ABS (cc)= 10.387447

[Calculations for time saved are in backup slides]

Statistical Tolerance Evaluation:

Upper Housing and One-way Valve/External Tube Housing

- Failure Mode
  - No Clearance Between Components

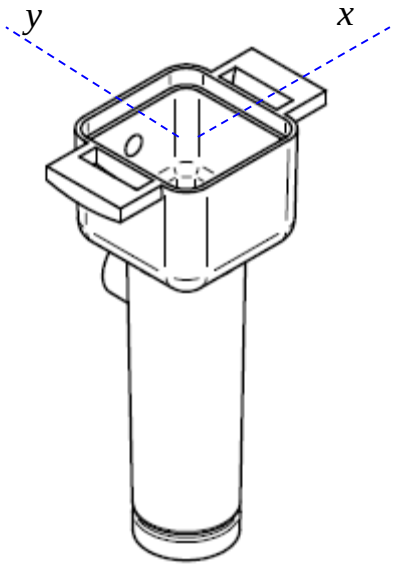


- Failure Equations

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

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

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



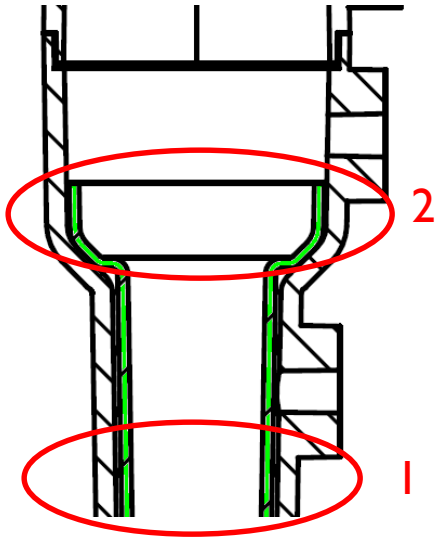
- Probability of Failure
  - Tolerance = 0.2mm

$P_{FAIL} \leq 0.0015\%$

Statistical Tolerance Evaluation:

Valve Body Housing / External Tube and Internal Tube

- Failure Mode
  1. No clearance between trocar sleeves.
  2. Leakage at the sealing part.
- Failure Equations
  1. $P_{(fail)} = D_{outer} - D_{inner} < 0$
  2. $P_{(fail)} = X_{outer} - X_{inner} > 0$
- Tolerance Select: 0.1 mm (Possible range: 0.2 – 0.05 mm)
- Clearance Select:
  1. $D_{outer} - D_{inner} > 0.2\ mm$
  2. $X_{outer} - X_{inner} = -0.2\ mm$ (locational interference fit)
- Probability of Failure
  1. 0 (<0.0015%)
  2. 0 (<0.0015%)



Advantages of Redesign

- Reduced number of sealing joints and a change in the way the components are assembled reduces leakage

- Reduced number of components and a change in the assembly procedure has increased the ease of assembly

- Reduced 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 of the desufflation button has reduced the chances of accidental desufflation

- Reduction in components and change in material has resulted in a cost reduction.

- The change in geometry and material has increased the strength of the insufflator tube

Disadvantages of Redesign

- Increase in outer tube diameter means an increase in the size of the incision to be made on the patient's body

- 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

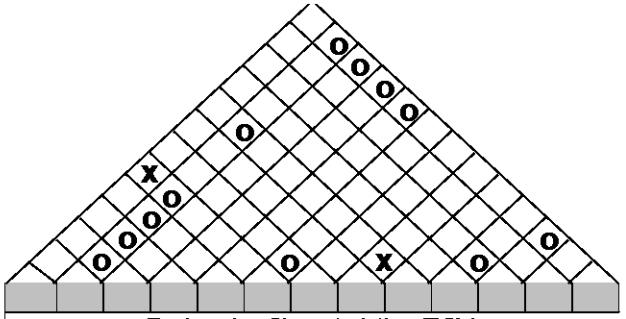
- Integration of components has made flapper valve housing more complicated and would increase manufacturing costs

- Change in the geometry of the outer tube results in a deep injection mold which would increase tooling and manufacturing costs

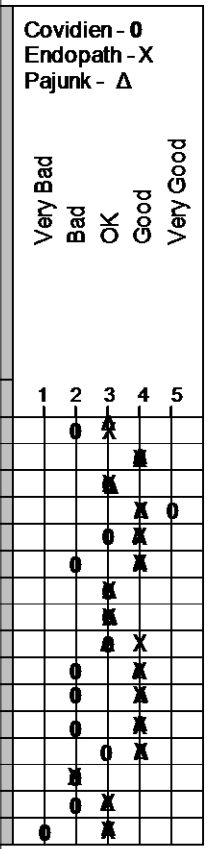
- The membrane at the end of the inner tube might reduce flow rate of air into body cavity

Questions?

Insufflator House of Quality



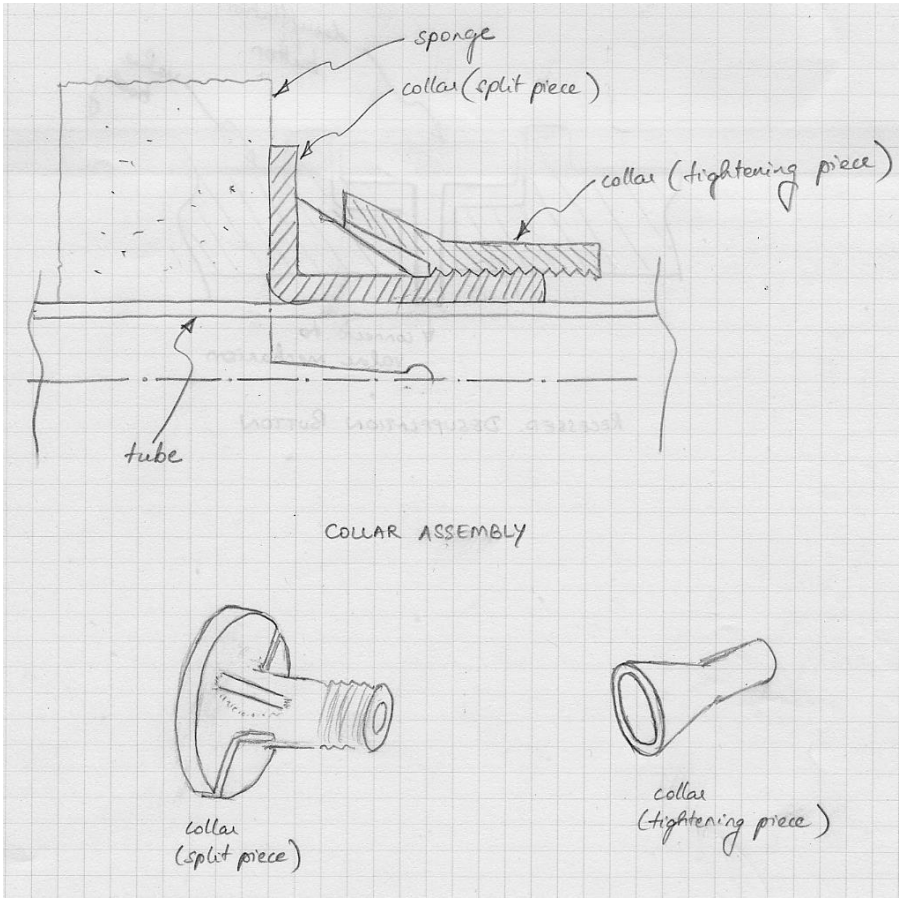
Orientation:		Engineering Characteristics (EC's)												
increase (+) decrease (-) target (o)		-	-	+	-	-	+	+	-	+	+	-	-	-
	Customer Importance	Allergenic components	Leakage from insufflated body	strength of collar	leakage rate from tube joint	leakage rate from valve body joint	Pressure rating of balloon	Thickness of balloon membrane	depth of balloon in body cavity	width of balloon in body cavity	Flapper Valve adapter size range	No. of adapter changes for diff. instruments	area in contact with user's hand	No. of components
Customer Requirements (CR's)														
Safety	insufflator body Should not leak	4		1		3	9							
	non-allergenic contact surfaces during use	5	3											
	balloon should not puncture	5						9	3					
	Minimum trauma to patient	5												
	air from body cavity should not leak	5		9		3	3							
	Non-allergenic contact surfaces even if punctured	3	9											
Ease of use	comfortable handle/ grip	3											9	
	easy to manipulate	3											3	
	should not interfere w ith inserted tools	3							9	1				
	insufflation pressure to be maintained	4		9		3	3			1				
	Wide range of instrument size that can be inserted										9	1		
Durability	Collar lock should not break	4			9									1
	valve should not get damaged by instruments	2												
Eco-friendliness	few er non-biodegradable parts	2												1
Assembly	Should be assembled easily	4												9
	Should be assembled quickly	4												3
Absolute Importance			42	85	36	39	63	45	15	27	7	0	0	36	54
Relative Importance			0.09	0.19	0.08	0.09	0.14	0.10	0.03	0.06	0.02	0.00	0.00	0.08	0.12
Units of Engineering Characteristics			[]	[]	psi	gallon/ sec	gallon/ sec	psi	in	in	in	in	F	mm^2	[]

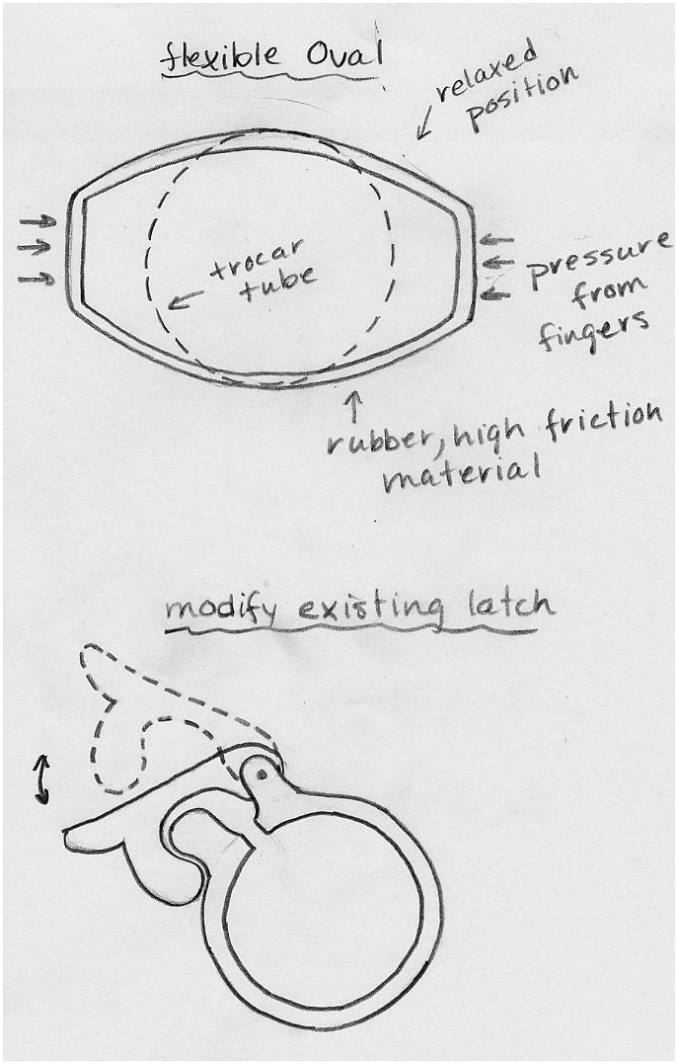


(I) Estimate of time saved during assembly

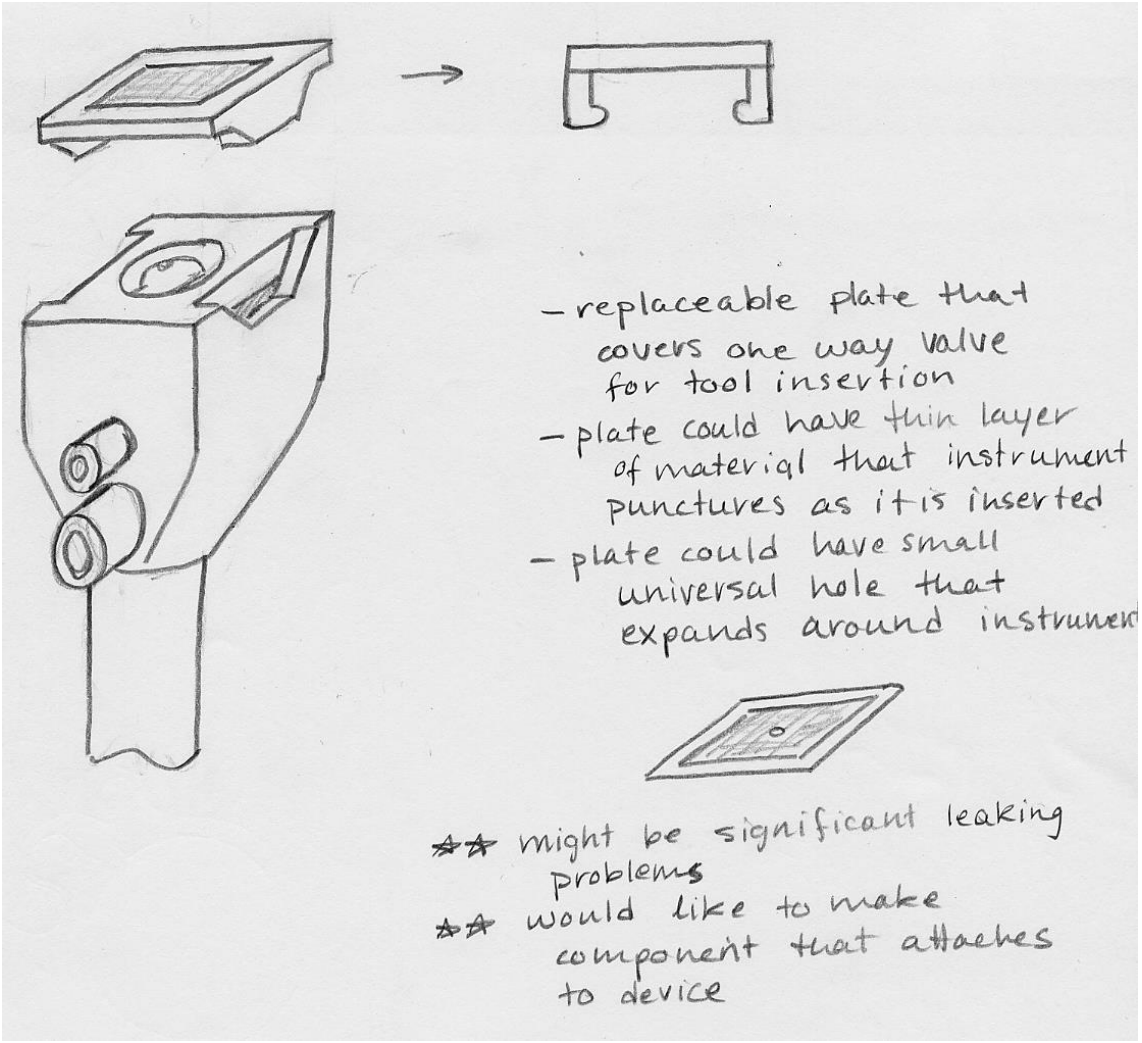
Part	Quantity	Current Manufacturing Process	New Manufacturing Process	Estimated Original Assembly Time (s)	% Time saved
Handle Assembly				**10**	**100.00**
Obturator	1	Injection Molded	N/A		
Handle	2	Injection Molded	N/A		
Sponge/Collar Assembly				**180**	**83.00**
Sponge	1		Not Changed		
Collar	1	Injection Molded	N/A (part of new latch)		
Pins	3	Purchased	Purchased		
Latch	1	Purchased	Purchased		
Latch-collar Link	1	Purchased	Purchased		
Upper Housing Assembly				**420**	**30**
Housing 1	1	Injection Molded			
External Valve/Valve Door	1		Not changed		
Spring	1		Not changed		
Push-Slider	1		Not changed		
Push Button	1		Not changed		
Seal	1		Not changed		
Housing 2	1	Injection Molded	Injection Molded		
Push Button Cover	1		Not changed		
Adapter Flap	1	Injection Molded	Injection Molded		
One Way Valve	1	Purchased	Part of tube assembly		
Balloon Inflation Port/Housing	1	Purchased	Part of tube assembly		
Balloon inflation Port Adaptor	1	Purchased	Part of tube assembly		
Balloon Inflation Port Sleeve	1	Purchased	Part of tube assembly		
Tube Assembly				**600**	**-15**
Outer Tube	1	Blow Molded	Injection Molded		
Inner tube	1	Blow Molded	Blow Molded		
One Way Valve	1	Purchased	Not changed		
Balloon Inflation Port/Housing	1	Purchased	Not changed		
Balloon inflation Port Adaptor	1	Purchased	Not changed		
Balloon Inflation Port Sleeve	1	Purchased	Not changed		
Latex Balloon			Not changed		
Outer Ring		injection molded	N/A		
Inner Ring		injection molded	N/A		
Silocone Coating			Not changed		
Sponge/Collar Assembly			Reflected above		
Overall Assembly				**60**	**20**
Upper Housing Assembly			Reflected Above		
Tube Assembly			Reflected Above		
Handle Assembly			Reflected Above		

Original Concepts: Latch





Original Concepts: Adapter Flap



Insufflator Design Concept.