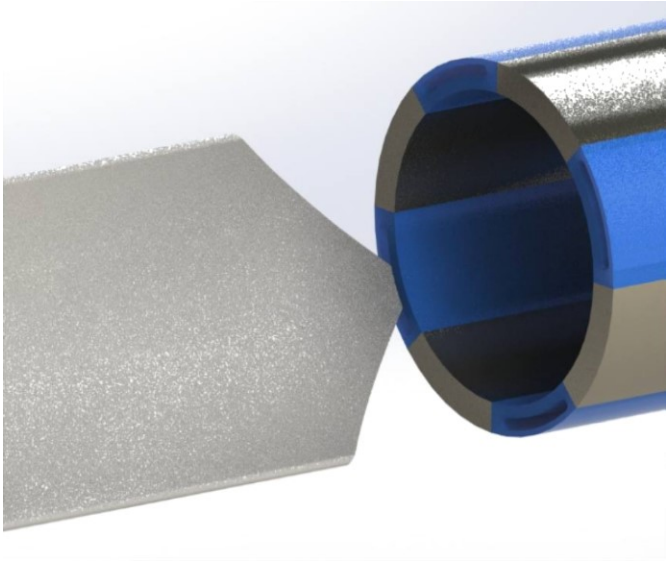
Project Proposal:

A Novel Adjustable Diameter Trocar Device

Engineering Science—Biomedical Systems Capstone Project



BME 489 – Group 201605

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Executive Summary

Globally, 15 million laparoscopic (minimal access surgeries) surgeries are performed every year, growing at a rate of 8.3%. Minimal access is achieved by medical devices called trocars placed through the abdomen and used to aid insufflating the abdominal cavity (pneumoperitoneum). Operations are then performed by passing medical devices and tools such as laparoscope and stapler through the cannula of the trocars. The global trocar market corresponds to $1.4 billion dollars, with 32% of the market share (~$450 million) consumed by the USA.

Surgeons try to minimize the scar and pain by selecting the smallest possible trocar size for the medical devices. However, in approximately 1/3 of laparoscopic operations, a small diameter trocar must be replaced by a larger diameter trocar to allow entry of a larger diameter tools needed during the operation. Trocar removal causes loss of pneumoperitoneum, which leads to impaired visualization of the area. Trocar re-entry may cause injury to internal organs, bleeding and may lead to traditional open surgery with high risk of infection.

This project aims to design a trocar with an expandable diameter cannula that would eliminate the need for trocar replacement. Such a device would prevent the loss of pneumoperitoneum and the subsequent injury risks due to trocar re-insertion. This in turn would reduce complications during surgery and improve patient recovery. In addition, such a device would increase efficiency of physicians performing laparoscopic surgeries as well as reduce waste, and cost associated with usage of multiple trocars. This would also make laparoscopic surgeries less costly and accessible to more patients.

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Project Description

1.1 Background and Motivation

Worldwide, 15 Million laparoscopic surgeries are performed annually, growing at a rate of 8.3% [1]. Laparoscopic surgery, also known as minimal access surgery, is a technique that allows operations to be performed through small incisions (5mm-15mm) [2]. Compared to traditional open surgery, laparoscopic surgeries reduce patient recovery time, pain, hemorrhaging and risk of infection. The abdominal cavity is insufflated with gas to create a working space within the body (pneumoperitoneum). Trocars are inserted through the abdominal wall, forming small ports that allow surgeons to pass surgical instruments (laparoscope, stapler) into the body without gas leakage. Commercially available trocars are sold in many sizes to accommodate medical devices with different outer diameters(OD).

Surgeons aim to minimize the scar size and pain by selecting the smallest possible trocar size for their tools. However, in approximately 1/3 of laparoscopic operations, a trocar must be replaced by a larger trocar to allow the entry of larger diameter tools during the operation [3]. Trocar replacement procedure can take 5-15 min and is achieved by pulling out the trocar and reinserting larger trocar through the original path [3]. This procedure carries high safety risks associated with the loss of pneumoperitoneum and trocar re-entry. Pneumoperitoneum loss leads to impaired visualization of the working space, while trocar re-entry carries risk of injury to internal organs, bleeding and further complications can lead to reverting to traditional open surgery which has higher risk of infection [4].

Clearly, there is a need for an adjustable diameter trocar that allows passage of tools of different ODs while eliminating the safety risks associated with the loss of pneumoperitoneum and trocar re-entry. Such a device would also reduce the required number of trocars per surgery and make laparoscopic surgeries more accessible to patients by reducing the cost per surgery and minimizing waste. Moreover, such trocar would reduce OR time, hence, further reducing the risk of anesthetic-caused complications and reducing hospital-incurred costs.

According to the MarketStrat, Trocar devices have a global market size of $1.4 Billion (USD), with the following approximate geographic split: Europe 25%, USA 32% (~$450 million), Japan 10% and rest of the world 33%. The market is dominated by Johnson & Johnson with 50% market share, followed by Covidien with 30% and Applied Medical with 15% [5] [1]. With the growing demand in the supply of trocars, cost per trocar plays an important role in the market. Although disposable trocars with a radially expanding sleeve system (VersaStep by Covidien and Flexipath by Ethicon) can accommodate trocars with larger sizes, these systems have proven to be unreliable since the sleeves leave fragments in the tissue and do not eliminate the risks associated with the loss of pneumoperitoneum and trocar re-entry [3] [6] [7]. Currently, no trocars with an adjustable diameter cannula exists on the market.

1.2 Project Goal

The goal of this project is to improve the design of trocars in order to reduce the safety risks associated with the replacement of small diameter trocars with larger diameter trocars. These risks are defined by i) the loss of the pneumoperitoneum (pressure), and ii) tissue damage. The latter can be further assessed by measuring factors such as recovery time (length of hospitalization), blood loss (volume), scar size, and patient pain (measured by patient satisfaction and/or dosage or number of painkillers). Reducing these risks will allow surgeons to perform trocar up-sizing safely and efficiently, and would eliminate additional pain and complications experienced by patient due to re-entry of trocars.

1.3 Project Requirements

This section describes the functional requirements, objectives and constrains relating to a minimum viable prototype and a product. These requirements are based on current market research and based on client-specific needs [3].

1.3.1 Functional Requirements

1.3.1.1 The device shall allow passage of surgical equipment with the following standard outer diameters, as requested by the client: 5mm, 10mm, and 12mm [8]. **(mm)**

1.3.1.2 The device shall maintain chosen trocar cannula's internal diameter (ID) until changed by the operator. **(mm, time)**

1.3.1.3 The device shall provide a seal to maintain required pressure of gas in the patient's body (Pneumoperitoneum) as determined by a physician. ***(cmH_2O)*** *In an adult the pneumoperitoneum is maintained at a maximum of 15cmH_2O while in infants the pressure is maintained at 4-5cmH_2O* [3].

1.3.1.4 The device shall fit securely at incision site without moving into/out of patient's body. **(Newton)**

1.3.1.5 The device shall connect to a standard Luer port and allow the passage of CO_2 gas. **(boolean)**

1.3.1.6 The device must be sterile or sterilisable via standard sterilization methods. *Standard sterilization methods include autoclave, ethylene oxide or gamma radiation.* **(boolean)**

1.3.2 Constraints

1.3.2.1 Total Prototyping Spending shall not exceed $750 **($ CAD)**

1.3.2.2 R&D, prototyping, testing and validation shall not exceed a time period of 2 months. **(Months)**

1.3.2.3 Product (not prototype) shall not have a shelf cost exceeding the value of 2 standard trocars of competitors**.** *This value is chosen because in the event replacing a smaller diameter trocar with a larger one, a minimum of 2 products are consumed.* **($ CAD)**

1.3.2.4 Device shall not pose any additional safety risks to the patient. **(boolean)**

1.3.2.5 Device shall not violate any following ISO safety standards followed by predicates: ISO10993-1, ISO10993-5, ISO10993-7, ISO10993-10, ISO10993-12 and ISO 11135-1 [9] **(boolean)**

1.3.2.6 The device design shall be feasible to be produced using existing manufacturing methods. **(time, CAD)** *This includes methods such as machining, moulding, and 3D printing*

1.3.3 **Objectives**

1.3.3.1 When using the device, operator should require less time to exchange surgical equipment of 5mm, 10mm and 12mm diameters than current practice. **(minutes)**

1.3.3.2 The device design should be scalable for volume production **(CAD/CAD)**. *This can be quantified as the ratios of cost of mass manufacturing (1000 devices) over cost of prototype.*

1.3.3.3 The device should reduce waste incurred during minimal access surgeries **(Device/Surgery)**. *This can be quantified by cost of operation and total number of devices used per operation.*

1.3.3.4 The device should be as durable as possible **(Months)**. *This can be quantified by length of time that the device remains fully functional and able to achieve all requirements mentioned above.*

1.3.3.5 The product should be designed such that it will follow the pathway for 510K approval within the USA at minimal cost and time. **(CAD, Months)**

1.4 Validation and Acceptance Testing

Prototyped design will be tested according to following non-clinical performance testing methods to ensure validity of the design. Prototype must meet minimum acceptance criteria to pass validation stage.

1.4.1 Dimensional Verification Test: This test aims to assess the trocar cannula diameter adjustment functionality. A small incision will be made on a foam using a scalpel and the trocar prototype will be inserted into the foam. Cannula of the prototype will be adjusted to ID settings (5mm, 10mm, 12mm) and a corresponding obturator with a matching OD will be penetrated through the cannula. Inner and outer diameters of the cannula and the trocar dimension will be measured with a caliper prior and after insertion of the obturator. The test passes if the difference of the before and after measurements for each of the settings is within 0.1 mm of the specified dimension of the design according to ISO18340 [9].

1.4.2 Mechanical Verification Test: aims to ensure that altered trocar diameter is securely locked to the desired diameter, and that mechanical parts are connected to each other and can withstand penetration forces. In order to achieve this, trocar will be inserted through a permanently deformable foam.

a. Stress Testing: Force will be applied onto the trocar vertically. Trocar must withstand minimum 45N of vertical penetration force [10].

b. Diameter Lock Test: A zip-tie with marked dimensions will be placed around the cannula of the trocar. A Force gauge will be attached to the zip tie and tension will be applied in an attempt to buckle the cannula of the trocar. This procedure will be repeated for all diameter settings of the cannula. The cannula must not to collapse under the applied force of 45N [10].

1.4.3 Peritoneum Pressure Seal Verification Test: aims to ensure that the proposed design can maintain pneumoperitoneum. Trocars cannula will be placed into the mouth of a toy balloon. A flexible tubing with luer connection will be secured to the luer valve of the trocar and the valve will be turned on allowing the air exchange. The balloon will be inflated by applying required positive pressure through the tubing. After the inflation is complete, the valve will be turned off and the tubing will be disconnected. The balloon will be inspected for any defects and air leaks. Then the balloon and the trocar will be fully submerged into the water for 3 minutes and the presence of air bubbles will be observed. The test will be repeated for each diameter size (5, 10 and 15 mm) after adjusting the cannula diameter and placing the related size obturator. Passing criteria is the absence of air bubbles.

In addition, chemical compatibility of material and sterility tests must be considered for the final product (Appendix C:) However, these are out of the scope of this proposal due to the time constraint.

2. Technical Design

2.1 Possible Solutions and Design Alternatives

2.1.1 Hose-clamp expand-and-lock mechanism (Appendix D:)

This design draws inspiration from the rigidity of hose clamps and the one-way locking mechanism of a zip tie. Several stiff belts providing resistance against compression are placed repeatedly within a mesh-supported cannula. The belt starts at the smallest size, with the excess belt wrapping around. The belt fastener is designed such that, with enough force, the belt will expand and lock at a wider diameter.

Belts are widened by inserting a rod (obturator) that has the diameter of the target size and a taper for easy insertion.

2.1.2 Insert-mediated expansion (Appendix E:)

This design features a cannula that features elastic pockets and stiff support regions that span the length of the cannula and alternate radially. The stiff regions form struts that support the cannula to keep it straight and resist compression. The elastic pockets expand when a shim is inserted. The shims will be of a specific width and will increase the diameter of the cannula by a specific amount. Shims will also provide additional support.

2.1.3 Overlap unfolding expansion (Appendix F:)

This design draws inspiration from the clasp mechanism that allows a metal watch to expand in diameter. Panels will span the length of the cannula, with a joint allowing panels fold. The panels will be folded to the smallest diameter at the beginning of the procedure. Knobs or dials can be used to rotate the panels around the joints and unfurl smaller panels. The panels will add to the circumference of the cannula and increase the diameter.

2.2 Assessment of Proposed Solution

This section aims to assess the ability of the proposed designs (section 2.1) to meet the project requirements (section 1.3). Project requirements were summarised into criteria for design selection (Appendix G: Proposed Solution Selection. Using a weighted decision matrix (Appendix G: Proposed Solution Selection criteria were weighted and designs were assigned scores. The "Insert-Mediated Expansion" concept is the highest scoring concept and hence will be pursued for further technical development and prototyping. The "Insert-Mediated Expansion" concept is the highest scoring concept and hence will be pursued for further technical development and prototyping.

One of the *advantages* of this concept is that the diameter expansion mechanism is easily tunable and repeatable. This concept does not contain complex mechanical parts that would be hard to seal, giving it

an advantage in prevention of CO_2 leakage when compared to other concepts. The lack of small parts or complex mechanisms means that the product easily be produced on a larger scale with simple processes. *Disadvantages* of this solution are that it may be difficult for a surgeon to insert a small shim into the pocket, increasing operation time and decreasing ease of use compared to the simple dial or expansion rod of the other designs. There is a *trade-off* in prototypability; while the simplicity of the design makes it easier to manufacture, there may be difficulties in finding elastic materials with the proper material properties within the time and resource scale of BME428. The soft regions may be less resistant to compression, however they may also allow the cannula to adapt to the surgical instruments that are inserted and increase sealing ability.

2.3 System Level Overview

The trocar is a well-established device widely used device for laparoscopic surgeries. The procedure for insertion and use of our trocar is the same as the current practice (Figure 1, steps 1-3). Our device adds a new step to this workflow that will allow surgeons to increase the diameter of the trocar during the procedure to allow the insertion of larger devices (Figure 1, step 4). Detailed information on how the fourth step is achieved and maintained can be seen in our system level diagram (Figure 2).

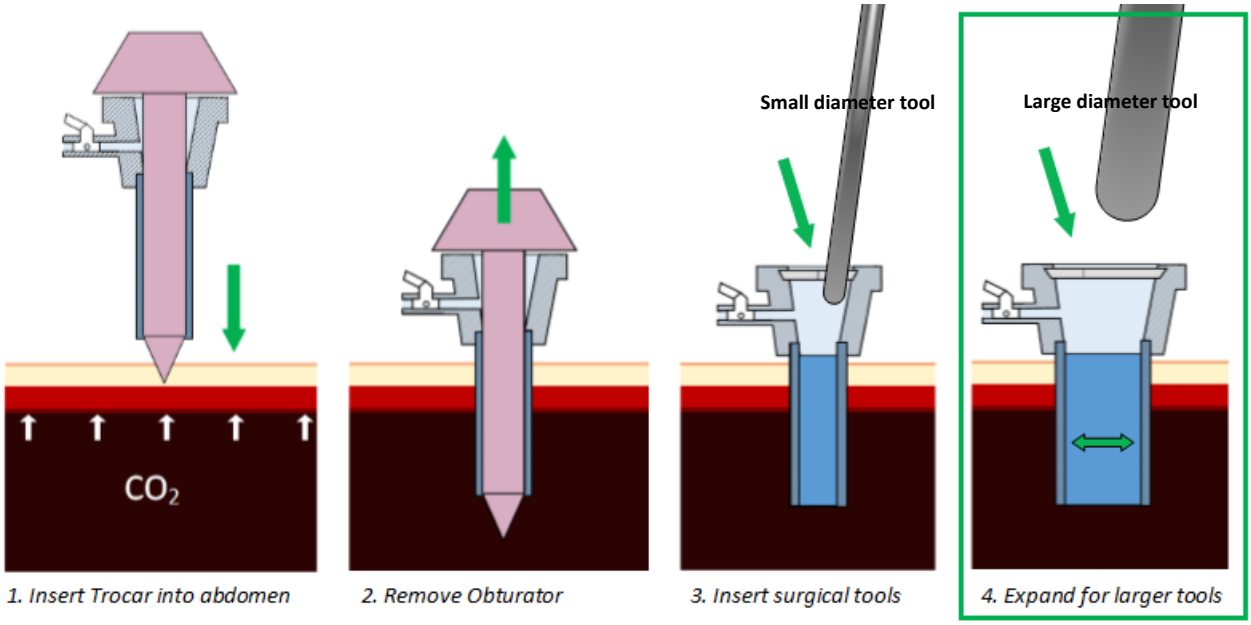

Figure 1 *Workflow Overview: Trocar use in surgical procedure*

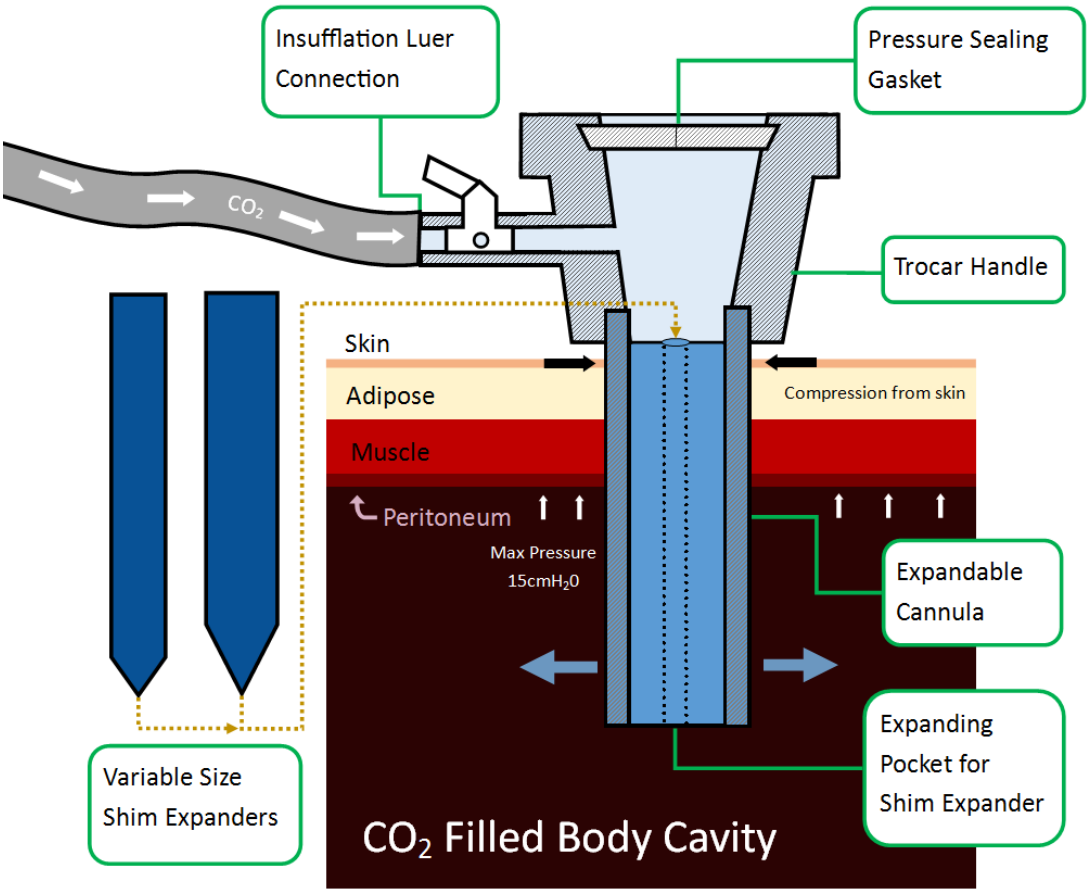

***Figure** 2 System Level Block Diagram*

2.4 Module Level Description

Expandable Cannula: The cannula of the trocar provides port that spans a region outside the body, skin, muscle and the peritoneum. The attachment between the cannula and the trocar handle must be leak-proof. The cannula must allow CO_2 gas and surgical instruments to pass into the body. It must also resist the compressive forces from the skin. In this particular concept, the cannula is made of several uniformly spaced arc-shaped, rigid parts with elastic pockets between them. The elastic pockets must be able to accommodate the various shim sizes without puncture or tearing.

Shim Expanders: The shim expander is a long, thin and rigid piece that is inserted into the cannula's elastic pockets. The shim acts as a spacer between the cannula's rigid pieces. Shims of different (incrementally larger) width are to be designed such that each larger shim selection will yield a larger

internal diameter of the cannula. Shims should be designed such that they can be easily inserted and removed from the elastic portion of the cannula.

Trocar Handle: The trocar handle is a rigid part that houses the cannula, pressure sealing gasket and luer connection for insufflation and must be designed in order to accommodate these three modules without air leakage at a pressure difference of $15cmH_20$. Special care must be taken to ensure that the trocar handle can accommodate the changing diameters of the cannula. The inner diameter of the trocar handle must be larger than the inner diameter of the cannula and cannot obstruct the insertion of instruments into the cannula.

Insufflation Luer Connection: The luer connection must fit the standard luer threads used to connect tubing within the operator room. The connection will also feature a leak-proof stopcock valve that capable of stopping airflow when the CO_2 hosing is not connected. The location of the luer connection on the trocar handle must be such that the CO_2 flowing from the connection will enter the body. Existing luer designs are standardized and compatible with our product, little redesign will be required.

Pressure Sealing Gasket: The pressure sealing gasket is an elastomeric material that forms a seal around surgical instruments as they are inserted. The gasket fills the space between the trocar handle and the surgical instruments, preventing the escape of air. The gasket system for the trocar must accommodate a much larger range of diameters than non-adjustable trocars.

3. Work Plan

3.1 Work Breakdown Structure (WBS)

For the sale of a medical device in the US market, the design and development of the proposed design must comply with Title 21, Section 820.30 of the US Code of Federal Regulations. The work breakdown structure (wbs) outlined below incorporates elements of this document [11, 12].

R – Responsible Member | A – Assisting Member

Task #	Task Name	Time (Days)	Shaurya Gupta	Zaid Atto	Kandice Lau	Seray Cicek
1	Planning Phase	10	A	R		
2	**Sub module prototyping**	**15**				
2.1	Prototype cannula with household materials (crude)	7	A		R	
2.2	Prototype rigid part of cannula	5	A		R	
2.3	Material selection: test range of elastic material of the cannula	7		A		R
2.4	Prototype elastic material with the rigid parts	7		A		R
2.5	Design the spacers that go between the rigid parts of the cannula	2	R		A	
2.6	Prototype the shim	3	R		A	
2.7	3D print obturators of different diameters	2	R		A	
2.8	3D Design and model the trocar handle	7		R		A
2.9	Specify design and material of trocar handle	5		R		A
2.10	Prototype design modules according to ISO specifications	2		A		R
3	**Integration**	**15**				
3.1	Integrate elastic and rigid portion of the cannula	5	A		R	
3.2	Integrate shim with rest of cannula	1	R		A	
3.3	Integrate trocar handle with rest of cannula	5		R	A	
4	Troubleshooting	14	R		A	
5	Validation and Testing	10	A			R
5.1	Validation Protocol Design	3	A			R
6	Final Report Writing	12			R	A

3.2 Gantt Chart

Please see Gantt Chart in Appendix H:.

3.3 Financial Plan[1]

Type	Item #	Item	Units Req.	Unit Price	Total Cost*
Costs Covered by Students	1	3D Rapid Prototyping	1	$10/cartridge	$200
	2	Machine shop metal (Aluminum Tubes)	5	$30	$150
	3	Machine shop plastic	5	$5/ft	$25

[1] The costs displayed in the Financial Plan table are price estimates based on the cost quoted for each item at the time of writing of the proposal

	4	Validation Tests (Pressure seal test, dimensional verification test, secure fit test, failure stress test)	n/a	n/a	$50
	6	Luer Locks	10	$5	$50
	7	Rubber Gaskets	10	$2	$20
	8	Miscellaneous Costs	n/a	n/a	$100
Resources Supplied	1	Industrial Trocars provided by SickKids Client	3-5	$0	$0
	2	Testing Equipment/Tools (from Design Studio)	1	$0	$0
	3	Software (SolidWorks CAD)	2	$0	$0
				Total	$595

3.4 Feasibility Assessment

3.4.1 Resources

Our team members possess the required engineering technical skills to design and prototype the proposed design. These skills include: computer aided design (CAD) and modeling, computer aided simulation, manufacturing methods such machining (Lathe, Mill, etc…) and experimental setup and testing. Our team requires access to external resources such as scientific literature, industry standards and guidelines (ISO, FDA). External resources also include design studio space, prototyping tools and equipment (e.g. 3D printers) in addition to other medical tools from SickKids.

3.4.2 Risk

The main risk involved in the proposed design is the interface between the rigid and flexible components. Flexible and rigid interfaces can be failure points when glued or mechanically connected to each other. In the industrial scale, this problem can be eliminated with injection molding. Due to the limited resources, first the cannula of the trocar will be prototyped with 3D printer and stretchable household materials. In case of failure different combinations of materials such as machined metals will be considered. If this milestone cannot be achieved by the end of October, conceptual designs mentioned in section 2.1 will be revisited and hybrid options will be considered.

References

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[11] U.S. Food and Drug Administration, "Design Control Guidance For Medical Device Manufacturers," 1997.

[12] Food and Drug Administration, Department of Health and Human Services, "Electronic Code of Federal Regulations (e-CFR): Title 21 Food and Drugs," 2016.

Appendix A: Report Attribution Table

R= Responsible Member

A= Assisting Member

Section	Sub-Section	Shaurya Gupta	Zaid Atto	Kandice Lau	Seray Cicek
	Executive Summary		R	A	A
Project Description	**Background and Motivation**				R
	Project Goal		R		
	Project Requirements	A	R	A	A
	Validation and Acceptance Tests		A		R
Technical Design	**Possible Solutions and Design Alternatives**			R	
	Assessment of Proposed Design		R	A	A
	System-level overview			R	
	Module-level descriptions		A	R	
Work Plan	**Work breakdown structure (WBS)**	R	A		A
	Gantt chart			R	A
	Financial plan	R			
	Feasibility Assessment (resources, risks	A	A	A	R
	Formatting	R	A	A	
	Proof reading	A	R	R	A

28 Sept. 2016

28 SEP 2016

Shaurya Gupta

28/09/2016

28/09/2016

Appendix B: Glossary

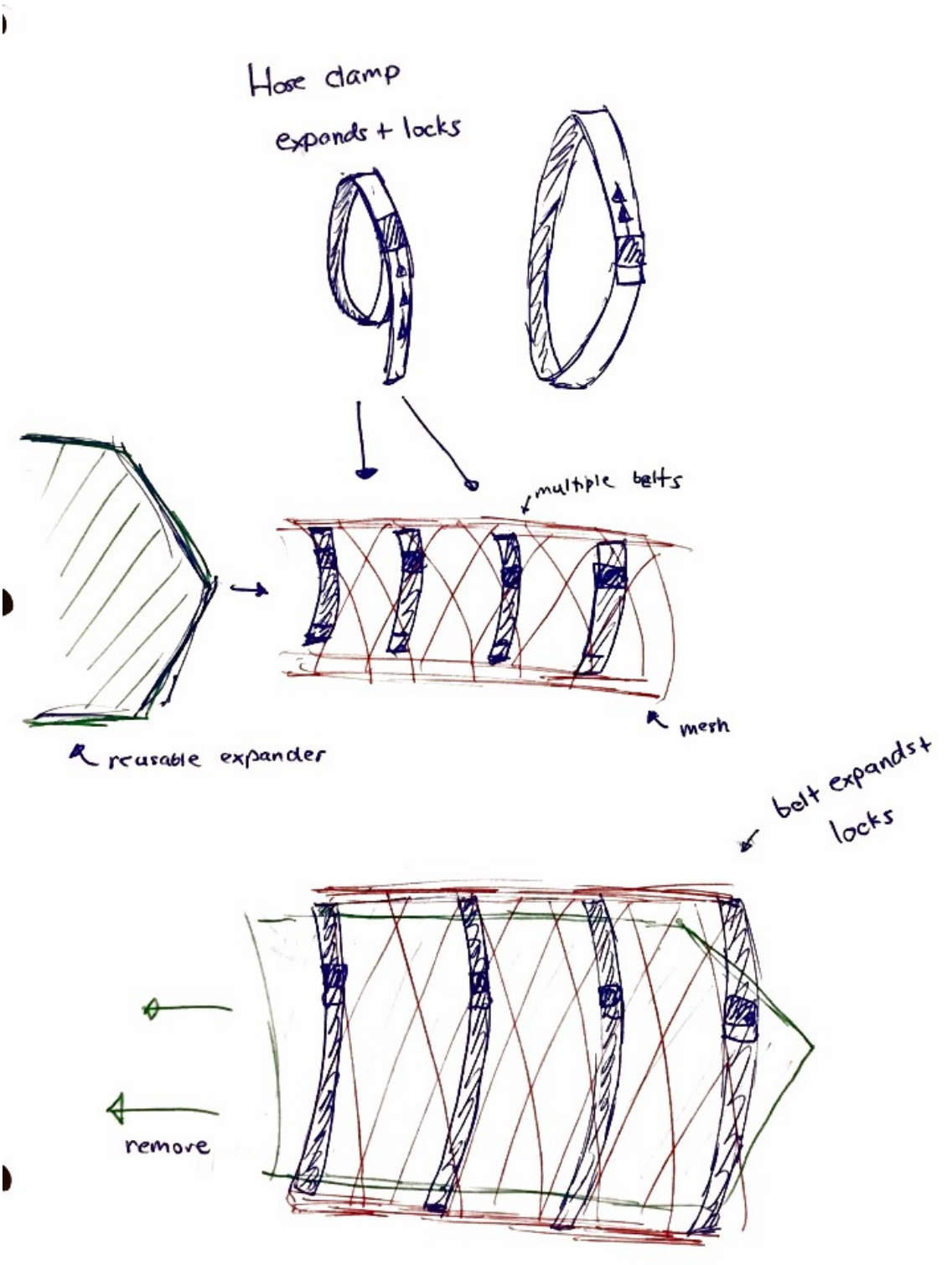
Term (Acronym)	Definition
Cannula	Thin tube section of the trocar used to create a rigid port in the abdominal wall.
Insufflation	Blowing of a gas (usually CO_2) into a body cavity.
Inner Diameter (ID)	Inner width of a hollow medical device.
Laparoscopic Surgery, Minimally Invasive Surgery (MIS) or Minimal Access Surgery (MAS)	Modern surgery technique that allows operations to be performed through small incisions (5mm-15mm).
Obturator	Part of the trocar used to penetrate the abdominal wall.
Open Surgery	Traditional surgery technique in which longer incisions are made to have direct access to internal organs.
Outer Diameter (OD)	Maximum external width of an medical device throughout the length of the portion to be inserted.
Pneumoperitoneum	Abnormal inflation of abnormal cavity, a technique used to provide better visualization and navigation during MIS surgeries.
Trocar	A medical device used to create a port for inserting medical devices during laparoscopic surgeries. It is made up of an obturator, cannula and a seal.

Appendix C: Additional Testing Required for Product Validation

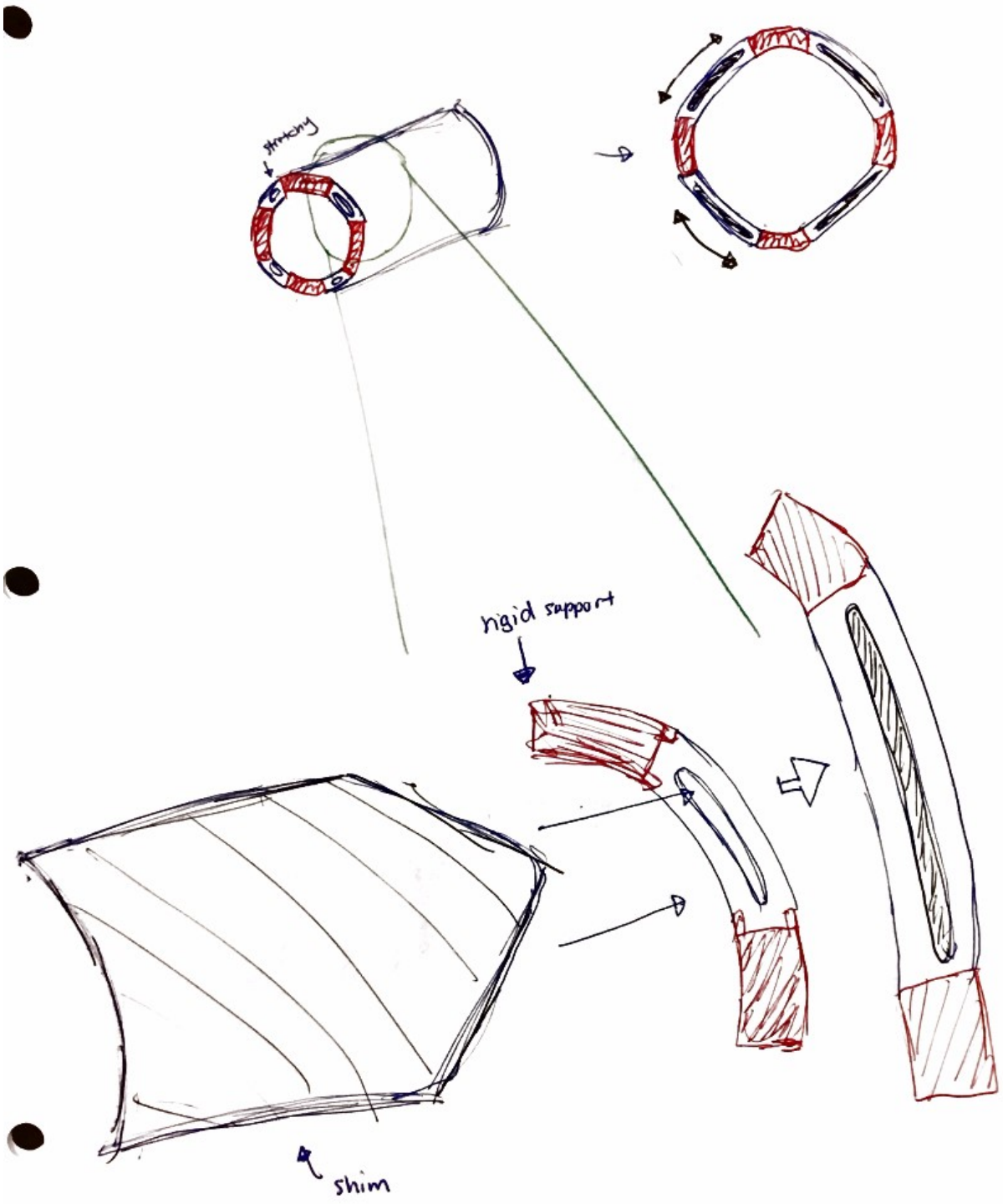
Sterility Test: This test proves that designed prototype can be sterilized by using autoclave, ethylene oxide or gamma radiation techniques. Sterilized prototype will be pressed against LB contact plates. Inner cannula of the trocar and surfaces that cannot be contacted by agar contact plates will be swabbed with sterile swabs. Swabs will be then plated on LB plates. Plates will be incubated under 37 degrees for 14 hours and looked for colony forming units. Acceptance criteria is presence of no CFU in all incubated plates.

Chemical Compatibility Assessment: This study is conducted to prove that extractables and leachables exposed to patients pose a negligible safety concern and selected material is safe to use for FDA Class II materials. This assessment will also estimate the shelf life and degradation of the product to assess chemical compatibility for the intended use. Selected polymer extractables and leacheables, and degradation data will be extracted for the autoclaved material. Calculations will be performed according to the worst case scenario assumptions and OR exposure time. Acceptance criteria is absence of carcinogenic leachables and degradation time greater than 1 year. Selected chemical must also be suitable for autoclave, ethylene oxide or gamma radiation sterilization without changing its chemical properties.

Appendix D: Hose-clamp expand-and-lock mechanism



Appendix E: Insert Mediated Expansion



Appendix F: Overlap unfolding expansion

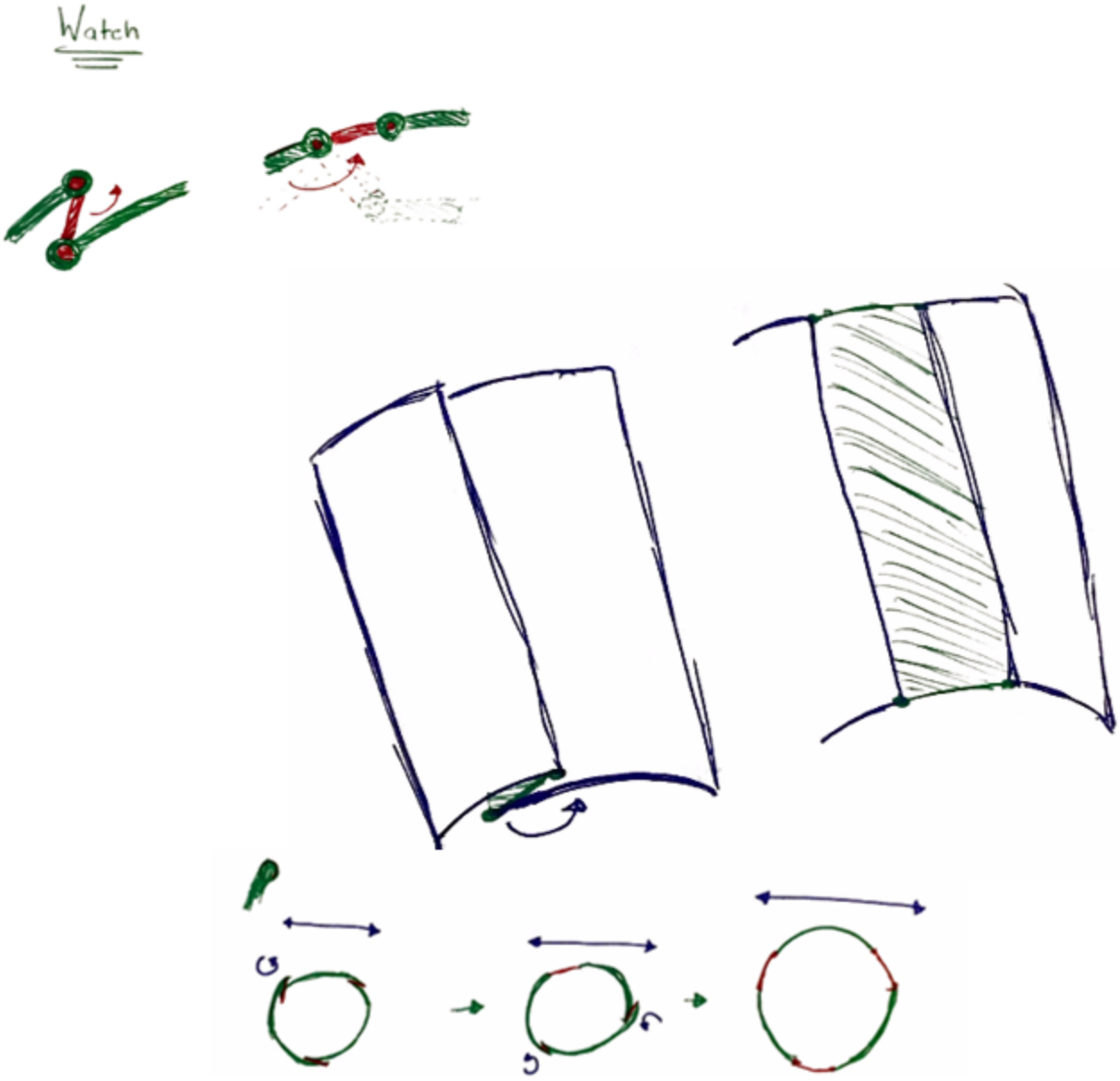


Figure 3 Overlap unfolding expansion

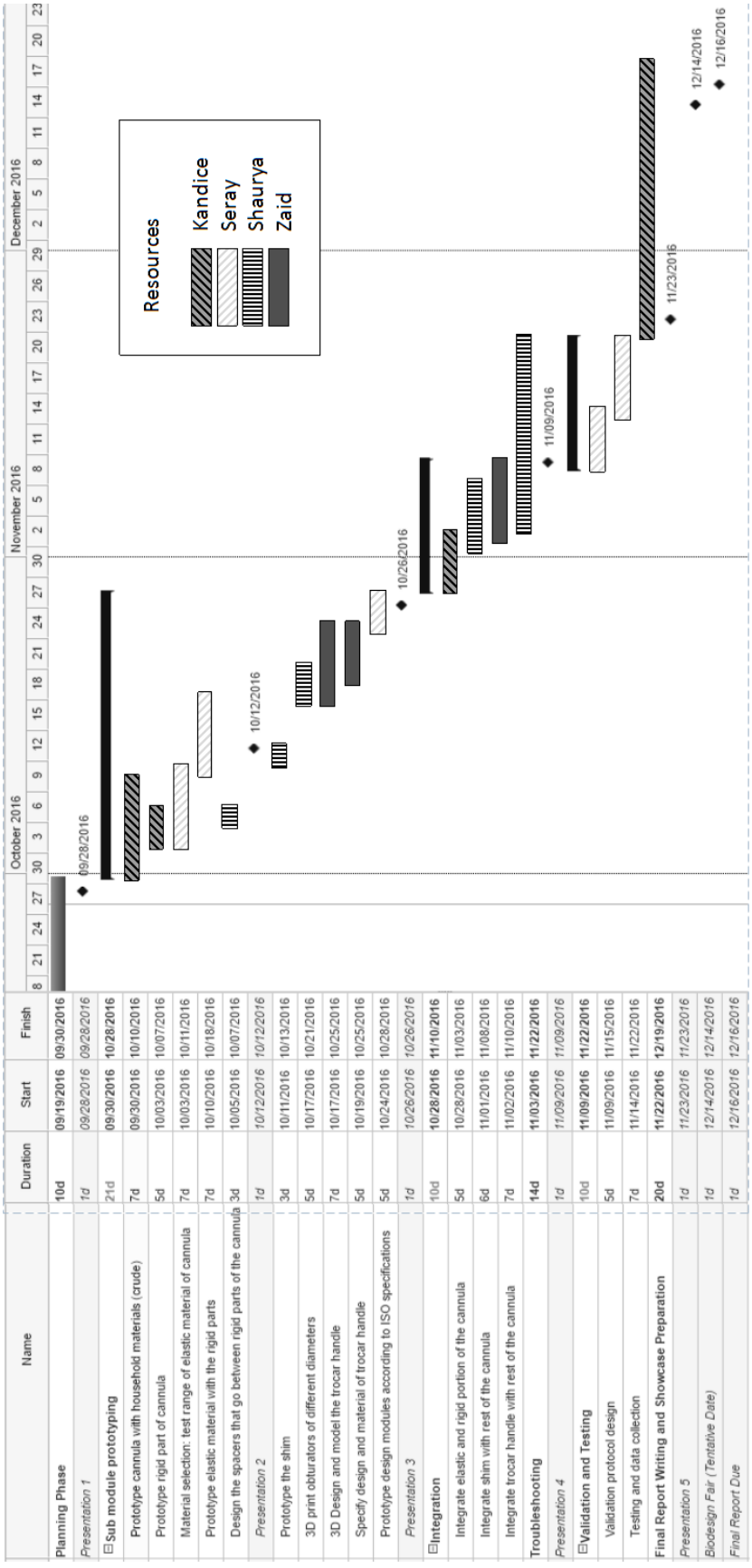
Appendix G: Proposed Solution Selection

Weighted decision matrix is used to select a candidate design for prototyping. Selection criteria stem from the requirements section. The weights are decided based on a 1-5 scale in terms of their importance to the project goal. The scores for each of the designs are determined as an average of 3 assessments and are multiplied by the weight factor. The total score is the sum of each weighted score for each of the proposed designs. The highest scoring device is the insert-mediated expansion and hence this concept will be pursued for further technical development and prototyping.

Table 1 Weighted Matrix for Concept Selection

Criteria for selection	**Relevant Requirements, objectives and constraints**	**Weight (1-5)**	**Design Scores (out of 10)**		
			Hose-clamp expansion and locking	**Insert-Mediated Expansion**	**Overlap unfolding expansion**
Expansion and secure locking of cannula ID	1.3.1.1 1.3.1.2	4	9, 8, 8, 9	8, 8, 8, 8	6, 5, 5, 5
Maintaining Pneumoperitoneum (air tight seal)	1.3.1.3 1.3.1.4 1.3.1.5	4	6, 6, 8, 7	8, 8, 7, 9	7, 6, 5, 6
Manufacturability (feasibility, sterilisablity, ISO compatibility, regulatory pathways, scalablility)	1.3.1.6 1.3.2.5 1.3.2.6 1.3.3.2 1.3.3.5	3	8, 6, 7, 8	9, 10, 9, 7	6, 5, 6, 6
Cost of Prototype and final Product	1.3.2.1 1.3.2.3	2	5, 4, 4, 5	7, 6, 7, 6	8, 8, 8, 8
Design Feasibility (within scope of BME489)	1.3.2.2 1.3.2.1	5	6, 6, 7, 7	9, 8, 9, 7	6, 5, 6, 5
Safety	1.3.2.4 1.3.3.1	5	7, 5, 7, 4	8, 8, 9, 8	7, 6, 8, 8
Device lifetime	1.3.3.3 1.3.3.4	1	4, 4, 2, 5	6, 7, 5, 5	8, 8, 9, 8
Total weighted score (out of 240)			156.75	**192.3**	150.25
Normalized score (out of 100)			65.3	**79.8**	62.6

Appendix H: Gantt Chart



Name	Duration	Start	Finish
Planning Phase	**10d**	**09/19/2016**	**09/30/2016**
Presentation 1	*1d*	*09/28/2016*	*09/28/2016*
Sub module prototyping	*21d*	**09/30/2016**	**10/28/2016**
Prototype cannula with household materials (crude)	7d	09/30/2016	10/10/2016
Prototype rigid part of cannula	5d	10/03/2016	10/07/2016
Material selection: test range of elastic material of cannula	7d	10/03/2016	10/11/2016
Prototype elastic material with the rigid parts	7d	10/10/2016	10/18/2016
Design the spacers that go between rigid parts of the cannula	3d	10/05/2016	10/07/2016
Presentation 2	*1d*	*10/12/2016*	*10/12/2016*
Prototype the shim	3d	10/11/2016	10/13/2016
3D print obturators of different diameters	5d	10/17/2016	10/21/2016
3D Design and model the trocar handle	7d	10/17/2016	10/25/2016
Specify design and material of trocar handle	5d	10/19/2016	10/25/2016
Prototype design modules according to ISO specifications	5d	10/24/2016	10/28/2016
Presentation 3	*1d*	*10/26/2016*	*10/26/2016*
Integration	10d	**10/28/2016**	**11/10/2016**
Integrate elastic and rigid portion of the cannula	5d	10/28/2016	11/03/2016
Integrate shim with rest of the cannula	6d	11/01/2016	11/08/2016
Integrate trocar handle with rest of the cannula	7d	11/02/2016	11/10/2016
Troubleshooting	**14d**	**11/03/2016**	**11/22/2016**
Presentation 4	*1d*	*11/09/2016*	*11/09/2016*
Validation and Testing	10d	**11/09/2016**	**11/22/2016**
Validation protocol design	5d	11/09/2016	11/15/2016
Testing and data collection	7d	11/14/2016	11/22/2016
Final Report Writing and Showcase Preparation	**20d**	**11/22/2016**	**12/19/2016**
Presentation 5	*1d*	*11/23/2016*	*11/23/2016*
Biodesign Fair (Tentative Date)	*1d*	*12/14/2016*	*12/14/2016*
Final Report Due	*1d*	*12/16/2016*	*12/16/2016*