Torq Medical

Business Plan

Version 1.0
February 13, 2017

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Prepared for:
2017 Life Sciences Start-Up Competition
Life Sciences Institute & e@UBC

1. Executive Summary

Our company's mission is to provide affordable, high quality, tourniquets for the developing world. Springboarding off of initial grant funding provided by UBC's Engineers in Scrubs (EiS) program, an NSERC-funded Collaborative Research and Training Experience (CREATE) program, Torq has developed a new tourniquet that meets the specific needs of low-resource hospitals. Our device, RightCuff, has the potential to make a positive impact by enabling safer, more reliable orthopaedic surgeries.

2. Market Analysis

2.1. Problem

Tourniquets are used in a variety of orthopedic surgeries in order to prevent blood flow to the limb on which the operation is conducted. Restricting blood flow during surgery enables the surgeon to operate with better visibility, and improves surgical outcomes. However, health care providers in low-resource hospitals must often resort to using rubber tubing as a makeshift tourniquet because conventional tourniquets are not available. The surgeon or nurse will tie rubber tubing tightly around the patient's limb in order to occlude blood, with no way of telling what pressure is being applied. Prolonged exposure to high pressures may cause lasting adverse health outcomes to the patient such as nerve and tissue damage. These low-resource hospitals face this challenge because there is no product on the market that can meet the associated needs. These hospitals require an affordable method of preventing blood flow without causing tissue damage, that does not rely on wall power.

2.2. Market Need

The customer base consists of low-resource hospitals conducting orthopedic and plastic surgery throughout Africa, Southern Asia and Central and South America. Our market entry point with this product will be targeted at countries with a high density of low-resource hospitals and similar regulatory requirements, as identified in Section 4.2. The purchasers for the hospitals work in collaboration with surgeons in order to determine which products to purchase, so it is important to engage both of these stakeholders. Our product should lead to fewer surgical complications and better reliability for surgeons. It should also lead to fewer post-surgery, patient injuries, which negatively impact both the health care provider and the patient by leading to increased hospital visits and recovery time.

2.3. Market Size

The global tourniquet market was valued at $184.6 M (USD) in 2014 and is expected to grow to $408.6 M by 2023.[1] Hospitals are the largest end-users of tourniquets, accounting for 73.3% share of the global market.[2] The market size for RightCuff is estimated at $8.65 M (USD) per year based on entry into the African, South American and Asian markets.
The groups of people that will be directly impacted by RightCuff are patients and their families, surgeons, nurses, government officials and legislators, patient advocacy groups, and hospital administrators.

3. Competition

3.1. How are Customer Needs Addressed Today

There are four basic tourniquet styles in use in various hospitals today, each with their own advantages and disadvantages: automatic pneumatic tourniquets, manual pneumatic tourniquets, pre-sized Esmarch tourniquets and basic Esmarch tourniquets (e.g. simple rubber tubing). Photos of these tourniquets can be found in Figure 1 in the Appendix. Currently, there are no tourniquet designs suitable for use in low-resource hospitals that are reusable, unreliant on wall power, and prevent nerve/tissue damage to patients.

3.2. Environmental Scan

Competitors	Product Name, Cost, Detail	Stage of Developm-ent	Academic Connection	Patents	Notes
Pyng Medical	-MATResponder -USD39.00 -Dial operated tourniquetl	On market	N/A	Yes: Publication #: US7582102 B2	-No pressure indication or control -Target market is EMS and military
Western Clinical Engineering Ltd, Zimmer Biomet Holdings Inc., and >50 companies	-Automatic pneumatic tourniquet -USD300 - 400 -State of the art and	On market	James A. McEwen, inventor of automatic pneumatic tourniquet, is an adjunct	Yes: >250 patents owned by inventor,	-Requires power -Expensive to purchase

selling automatic pneumatic tourniquets	standard of care in developed countries -Microcontroller regulates air pressure		professor at UBC	James A. McEwen	
OHK Medical Device Ltd	-HemaClear™	On market	N/A	Yes: PCT#: PCT/IL2002/000992	-Single-use

3.3. Competitive Advantage

The RightCuff is the only tourniquet that fulfills all of the specific needs present in low-resource hospitals. The RIghtCuff is the only multi-use, affordable product available that easily applies the correct pressure to patient's limbs without requiring any electricity. Our competitive advantage is underscored by the fact that these hospitals need to resort to makeshift tourniquets because there is no product that meets all of their requirements.

4. Commercialization Plan

4.1. Science / Technology Overview

The RightCuff is an easy-to-use surgical tourniquet that prevents blood flow to the applied limb without causing tissue damage. The device is affordable, durable, does not use any electricity, and is therefore tailor-made to suit low-resource environments.

4.2. Growth Strategy

The product will be initially be introduced in Uganda through our contacts at Mulago Hospital in order to garner interest and demonstrate functionality. We will then expand and distribute in four countries in East Africa: Uganda, Kenya, Tanzania, and Ethiopia. The ideal distributor will have an existing orthopaedic product line, and connections with low-resource hospitals that fit our need profile.

After establishing the current device in low-resource hospitals in east Africa, small changes can be implemented to create a second generation of the device for hospitals that are less resource-constrained. This second market will include hospitals that require an affordable product, but have access to consistent power. The second generation product will be designed to fulfill the specific needs of this group of customers.

4.3. Milestones

Milestone	Anticipated Date	Costs	Resources
Finalize prototype	June 30, 2017	$2,000	3D printer+material
Device Testing+Refinement	September 1, 2017	$1,000	Pressure sensors+acquisition instruments
Provisional filling	September 10, 2017	$4,000	N/A
Set up manufacturing line	October 15, 2017	$10,000	Manufacturing workspace
Establish sales connections in target markets	Uganda - January 1, 2018	$10,000	Flights
FDA approval (Class II 510K)	March 1, 2018	$2,345	N/A
National Drug Authority (Uganda) approval	May 1, 2018	$100	N/A
PCT filing	September 9, 2018	$6,000	N/A

5. Financial Plan

5.1. Financial Needs and Justification

At this stage, the primary financial needs of the company are centred around developing the product and obtaining the necessary regulatory approvals to reach the commercial market. A breakdown of the monetary requirements for the upcoming phases of the project is presented in the following table.

Item	Cost	Justification
Product development	$5,000	Prototyping and testing
Regulatory fees	$2,345	FDA 510(k) cost for small business [3]
IP protection fees	$10,000	$6,000 patent application in Canada + $4,000 PCT application to reserve international filing rights
Office space	$12,000/year	An estimate for rental space has been obtained from a local contact
Salaries for current team	$210,000/year	The 3 founders will make up the engineering & product development team
Salaries for new employees	$210,000/year	Marketing, sales, and finance personnel will be hired, +25% included for benefits

5.2. Fundraising plan

Funding Source	Founders	Grants	Incubators / Seed Funds	Individual / Group Donors	VC
Stage	Idea / Prototype	Idea / Prototype	Idea / Prototype	Idea / Prototype	“Traction”
Amount	$1k - $5k	$20k - $30k	$5k - $20k	$50k - $200k	$300k - $580k
Form	Convertible debt	N/A	Equity	Equity	Equity
Dilution	N/A	0%	1.25 - 5%	3.75% - 15%	15% - 29%
Timescale	Days	Weeks	Weeks	Months	Months
Exit	Any	Any	>$400k	>$1.3M	>$2M

5.3. Exit

The exit strategy for Torq will be to establish relationships with existing distributors in our target markets. We will engage in distribution contracts and licensing agreements with entities that have the network and capability to deliver our product to the target audience in our selected countries. The revenue generated from initial sales will be used to expand our market, and eventually develop a second generation product targeted at a hospitals with fewer constraints on resources. The ultimate goal of the company will be to have our IP and network connections acquired by a company with the manufacturing means and vision to bring our product to all low-resource hospitals that stand to benefit from it.

6. Team

The founding team consists of three Masters students in biomedical engineering, with backgrounds in mechanical engineering. Our combined skills will enable us to drive the product development and manufacturing side of the company, and we will hire outside talent to drive the sales and finance aspects.

Company Composition				
R&D Team	**Production Team**	**Sales and Marketing Team**	**Accounting and Finance Team**	**Advisory Members***
Axel Chu Liam Sharkey Luke Haliburton	Axel Chu Liam Sharkey Luke Haliburton	To hire	To hire	Dr. Piotr Blachut Lawrence Buchan Sean Lumb

**Advisory members’ credentials:*

- **Dr. Piotr Blachut**: Clinical Professor, Orthopedics (Faculty of Medicine), University of British Columbia
- **Lawrence Buchan**: Operations Director & Co-Founder, Arbutus Medical
- **Sean Lumb**: Director, New Ventures, entrepreneurship@UBC

7. References

[1] Tourniquet Market http://www.prnewswire.com/news-releases/tourniquet-market-expected-to-reach-us-4086-mn-globally-in-2023-emerging-trends-and-new-technologies-research-2016-2024---tmr-581647081.html

[2] Tourniquet market share
http://www.transparencymarketresearch.com/pressrelease/tourniquet-market.htm

[3] FDA 510(k) cost
http://www.fda.gov/ForIndustry/UserFees/MedicalDeviceUserFee/ucm452519.htm

[4] Healthcare spending in 2014, by country
https://www.emergogroup.com/resources/worldwide-health-expenditures

8. Appendix

Figure 1: Types of tourniquet from left: automatic pneumatic tourniquet, manual pneumatic tourniquet, pre-sized Esmarch tourniquet, basic Esmarch tourniquet

Chart 1: Global Tourniquet Market Share in 2014, by End-User [2]

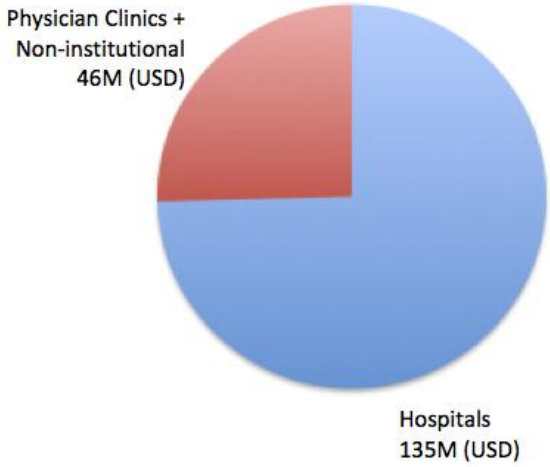

Chart 2: Global Tourniquet Market Share in 2016, by Product (Estimated)

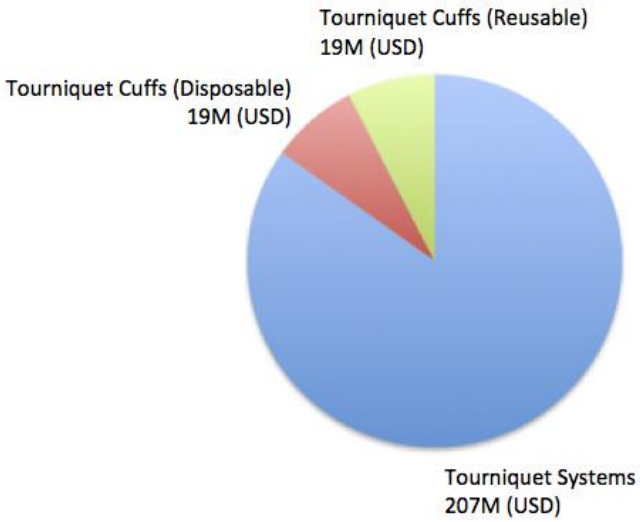

Chart 3: Global Tourniquet Market Share in 2016, by Geography (Estimated) [4]

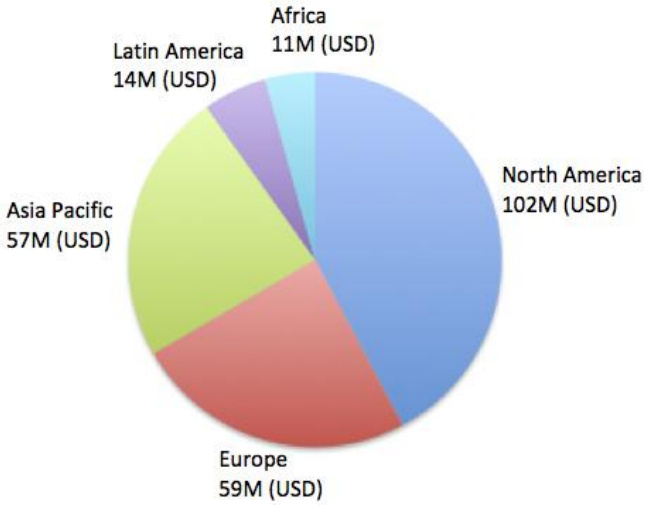

Table 1: Stakeholder Analysis

Stakeholder	Benefits	Costs	Net impact
Patient	Reduction of postoperative complications	Additional cost of care	+
Surgeon/nurses	Shorter surgical preparation period	Learning to use a new device	+
Government officials/legislators	Improved long term cost of care (fewer patients readmitted)	Higher short term cost of care	+
Patient advocacy groups	Improved quality of care/disability reduction	Possible additional cost	+
Administrators	Fewer patients readmitted	Change in purchasing procedure	+