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From Malawi to Middlesex – The case of the Arbutus Drill Cover System as an example of the cost saving potential of frugal innovations for the UK NHS

Matthew Prime 1, Ibtehal Attaelmanan 2, Arjuna Imbuldeniya 3, Matthew Harris 4, Ara Darzi 5, Yasser Bhatti 6

1 Clinical Research Fellow, Institute of Global Health Innovation, Imperial College London, UK

2 Research Assistant, Institute of Global Health Innovation, Imperial College London, UK

3 Consultant Surgeon in Trauma and Orthopaedics, Chelsea and Westminster NHS Foundation Trust, West Middlesex University Hospital

4 Clinical Senior Lecturer in Public Health, Institute of Global Health Innovation and the School of Public Health, Imperial College London, UK

5 Director, Institute of Global Health Innovation, Imperial College London, UK

6 Research Fellow in Frugal Innovation, Institute of Global Health Innovation, Imperial College London, UK

Corresponding Author:

Dr Yasser Bhatti, Institute of Global Health Innovation, Division of Surgery, Imperial College London, 10th Floor, QEQM Building, St Mary's Hospital, Praed Street, London W2 1NY, UK Email: Yasser.bhatti@imperial.ac.uk Telephone: +447855773129

Collaborators:

George Garrad, Amy Darlington, and Axel Heitmueller of Imperial College Health Partners; Florin Gheorghe of Arbutus Medical

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ABSTRACT

Background:

Musculoskeletal disease is one of the leading clinical and economic burdens of the UK health system and the resultant demand for orthopaedic care is only set to increase. One commonly used and one of the most expensive hardware in orthopaedic surgery is the surgical drill and saw. Given financial constraints, the NHS needs an economic way to address this recurring cost. We share evidence of one frugal innovation with potential for contributing to the NHS' efficiency saving target of £22bn by 2020.

Methods:

Exploratory case study methodology was used to develop insights and understanding of the innovations potential for application in the NHS. Following a global search for potential frugal innovations in surgery, the Arbutus Drill Cover System was identified as an innovation with potential to deliver significant cost-savings for the NHS in the UK.

Results:

The Arbutus Drill Cover System is up to 94% cheaper than a standard surgical drill available in the UK. Clinical and laboratory tests show that performance, safety and usability is as good as current offerings in High Income Countries (HICs) and significantly better than hand drills typically used in LMICs. The innovation meets all regulatory requirements to be a medical device in the Europe and North America.

Conclusions:

The innovation holds promise in reducing upfront and lifespan costs for core equipment used in orthopaedic surgery without loss of effectiveness or safety benchmarks. However, the innovation needs to navigate complicated and decentralized procurement processes and clinicians and healthcare leaders need to overcome cognitive bias.

250 words

Keywords: Cost saving, orthopaedic surgery, frugal innovation, reverse innovation, NHS improvement.

INTRODUCTION

The primary objective of this paper is to present the Arbutus Drill Cover System, a promising medical device with significant potential for cost saving for the NHS. This work also reflects on the significant challenges faced by entrepreneurs and innovators as they seek to scale up promising ideas in the UK and further afield.

Traumatic injuries are one of the leading causes of disability and death worldwide, accounting for nearly 1 in 10 deaths each year [1]. 90% of injury deaths occur in low- and middle income countries (LMICs) [2]. Injuries in the UK result in a substantial population burden in terms of disability and premature mortality [3]. Musculoskeletal disease accounts for over 25% of surgical interventions within the NHS [4]. One of the critical kits commonly used in orthopaedic surgery is the surgical drill and saw. All orthopaedic trauma cases require a drill except closed reduction of fractures in children. Against a background of an ageing population and rise in non-communicable diseases there will be an ever-increasing demand for orthopaedic care. As trauma affects a relatively younger population, it accounts for more productive years of work lost than other illness, with an enormous economic and societal impact.

The significant £20-30K cost of current clinical surgical drills has meant that trauma and orthopaedic surgeons in LMICs resort to using imprecise and slow hand drills or unsterile hardware drills, with serious consequences, including disfigurement, severe infection and loss of life [5]. In 2012 the lead author undertook an orthopaedic fellowship at Beit-CURE International Hospital in Malawi, where he observed the practice of wrapping a commercially available hardware drill with an unsterile crude cover; a common practice across LMICs. At the same time, in Uganda a group of biomedical engineering students from the University of British Columbia also witnessed the same behaviours and sought to convert this *jugaad* practice into a frugal innovation through a structured innovation and design process [6, 7]. Arbutus Medical Inc. was incorporated in 2014 for the purposes of commercializing the company offering.

Through case study development, we sought to understand the conception, development and implementation of the Arbutus Drill Cover System for the purposes of assessing transferability to the NHS, specifically at the West Middlesex University Hospital.

METHODS

Over a two-year period the Institute of Global Health Innovation (IGHI) has conducted an international search for frugal innovations with potential application by healthcare providers in high-income countries (i.e. potential for reverse innovation) [8, 9]. In 2015 we conducted a global search of hundreds of cost saving innovations including products, processes, and policies that addressed all types and domains of healthcare [10, 11]. Key criteria used to evaluate frugality included affordability, adaptability, and accessibility. In 2016 we narrowed down this search to shortlist those related specifically to surgery with potential for piloting in the UK's NHS. One of the most promising offerings we found in surgery is the Arbutus Drill

Cover System. An exploratory case study methodology was used to collect information about the Drill Cover System and the company behind its development via a range of data collection techniques comprising observation, interview and documentary analysis, for the purpose of developing insights about the applicability of the innovation for the UK NHS. We focused more on the technology and its potential for piloting, though we also came to understand more about the organization backing this technology as part of assessing prospects for piloting and scaling. Researchers (IA/YB) undertook multiple telephone and face-to-face interviews with the co-founders of Arbutus Medical to understand the conception and development of the Drill Cover System. Concurrently, (MP/IA/YB) analysed documents related to the innovation including company presentations; laboratory findings; usability feedback; technical instructions and regulatory approval information. Subsequently, researchers (MP/YB/AI) undertook an international fieldtrip to Uganda and Kenya, where three hospitals were visited, to gain perspectives of the Arbutus Drill Cover System from frontline healthcare workers; this included observing the drill in surgeries and at the point of assembly and disassembly.

RESULTS

How was the innovation conceived?

In 2013, as part of the University of British Columbia's Engineers in Scrubs programme, a team of biomedical engineering researchers, orthopaedic surgeons, registered nurses, reprocessing staff, and health administrators from Canada and Uganda looked at pressing clinical needs at Mulago Hospital in Kampala, Uganda. They identified the problems arising from inadequate availability of expensive surgical drills and embarked on developing a solution. The project ideation and lead target market in East Africa is facilitated by urgency of need and lax regulatory enforcement. However, design, engineering, manufacturing, quality management system, as well as strategic and operational control are based in Canada.

What are the key features?

The Arbutus Drill Cover System is a sterilisable and reusable cover that fully encloses a hardware drill, transforming it into a surgical grade drill. The Drill Cover System consists of a robust, double-layered surgical-grade textile which attaches to a drill's mechanics via a waterproof chuck adapter interface (Figures 1-6). This creates a completely sealed barrier between the non-sterile drill on the inside and the sterile surgical field outside. The chuck has a lifetime of at least 600 use cycles when reprocessed appropriately. It can be autoclaved up to 75 times and will be sterile after 30 minutes exposure of steam autoclave at 121°C, or after 15 minutes at 131°C, either by using gravity displacement or pre-vacuum autoclaves [10].

Arbutus Medical Inc. provides two versions; the S, which is used with a surgical drill to increase uptime throughout the day and extend its lifetime by eliminating the harsh sterilization cycles that drills must otherwise undergo, and the Hex, which is used with a standard hardware drill. (For product suite, please see video supplement 1). It has been designed for easy assembly following sterile technique, and the cover material is soft enough

for the surgeon to control the drill through the fabric without hindrance. The textile and manufacturing techniques follow an AAMI/ANSI PB70 standard for Level 4 medical barriers. The Drill Cover is CE marked as a Class I medical device, registered with the US FDA and approved with Health Canada. Further tests are being conducted to re-classify the whole package of cover plus drill as a CE Class IIa device.

How does it work?

The Arbutus Drill Cover System is assembled by inserting a non-sterile hardware drill into a sterile cover. The bag edges are rolled down with fingers tucked under during loading, before being rolled back and sealed to encase the hardware drill. (For loading and assembly, please see video supplement 2). This is a standard process used in other types of surgery to provide a sterile barrier, most notably arthroscopic procedures, where a cover is placed over a non-sterilisable camera and light source.

Turnaround time between cases can be as quick as 1-minute, by switching out a soiled Drill Cover for a sterile one; permitting frontline staff to treat more patients with faster drill turn-around between cases. The Drill Cover can be used with both inexpensive off-the-shelf hardware drills, or with current surgical drills, thereby prolonging their lifespan by reducing wear and tear from repeated autoclaving and requiring the purchase of fewer clinical drills. Hence, while there is greater potential for cost saving in using the cover along with the commercial hardware drill, there are benefits to using the cover alone.

The benefit in using commercial hardware drills is the significantly lower upfront cost investment and the ability to easily replace the drills in the event of breakdown. The company recommends the Drill Cover System is paired with a DeWalt DCF610S2; an affordable and robust hardware drill carefully selected and tested to closely match the speed, torque, and power offered by surgical drills. The DeWalt drill is commercially and widely available in hardware stores around the world. User feedback we collected from surgeons suggests that in many cases they find the commercial hardware drill, specifically the DeWalt, to be ergonomically easy to use, small, compact, light, powerful, and overall better than a lot of old generation surgical drills used in the developing world and also many NHS Hospitals.

The DeWalt drill has been electrically tested to ensure there is no interference with other operating room equipment and tests show that the hardware drill battery lasts much longer and is cheaper to replace. The recommended DeWalt drill costs as little as £100 vs. £23-30K for a contemporary surgical drill, replacement batteries cost as little as £30 vs. £1500, respectively. As the DeWalt drill is a critical component of the Arbutus Drill Cover System, the company's regulatory and ISO 14971 Risk Management process takes in to account the safety and efficacy of the DeWalt drill when used as part of the system.

How has the company been funded?

Arbutus Medical Inc. was established in 2014 as a for-profit medical devices company funded by Grand Challenges Canada, a non-profit initiative funded by the Government of

Canada – with an initial investment of \$1 million. Prior to this the company received support from Canada based Coast Capital Savings Innovation Hub, a social venture accelerator operated by the UBC Sauder School of Business, and the Lean Launch Pad Accelerator program offered by entrepreneurship@UBC [12]. The company has also received funding from impact angel investors with a dual focus on financial and health impact returns. These include physicians, successful former and current entrepreneurs, family offices/foundations (e.g. Threshold Impact, D. Keith MacDonald Foundation), and sophisticated healthcare investors (Angel One Network, SWO Angels).

What is the business model?

Arbutus Medical Inc. seeks to sustain and expand its offering by earning a profit from the sale of the Arbutus Drill Cover System. Presently, Arbutus products are available in 15 countries, and the company hopes to expand its reach across Africa, Latin America, India, Turkey, and the Philippines in the near future. Most recently it has begun to explore markets in the US, Canada, South Africa, and the UK, with clinical pilots in the planning stages in each country. In the developing world it sells to hospitals through distributors.

A financial and economic model co-developed in partnership with Imperial College Healthcare Partners, a member organisation of the NHS academic health science network, and in conjunction with Arbutus Medical Ltd, evaluated initial capital investment based on recent and real purchasing data, as well as projected the 5-year costs of supplying the NHS.

At the national level, for example, if the NHS were to replace all incumbent drills with similar offerings, (approx. 5000 at estimated cost of £23K per drill), this could cost £115 million. However, if all of NHS providers were to move to the Arbutus Drill Cover System (estimated cost per drill £1500), it could cost as little as £7.5 million; an upfront saving of 94% in immediate capital outlay.

At the hospital level, for example, the total costs to equip and maintain surgical drill equipment for two theatres over 5 years would be £324,500 (11 drills at £23K per drill with annual battery replacement for years 2-5) while the Arbutus Drill Cover System would be £47,993 (2 drills + 2 saws; 22 initial linens; 14 p.a. replacement linens and 4 replacement batteries per drill for years 2-5), a saving of 85%.

What is the operating model?

Design, engineering and manufacturing are based in Canada while sales and marketing is spread globally, primarily in the developing world. Arbutus Medical has 9 full time employees and over half a dozen contractors and interns. The company's key performance metrics are both sales and revenues as any typical company, but also the impact that they have socially as measured by number of patients treated and disability avoided. The product's key performance metrics are number of cycles possible for delivering safe surgery and cost savings in comparison to competitors, as well as the ease of use and integration into existing surgical workflows.

How is the innovation being spread?

The development of the Arbutus Drill Cover System has always been grounded in the needs of frontline clinicians and patients, with a vision to provide increased access to safer surgery. As such they have developed a network of clinical champions, which have helped spread knowledge about the innovation and the company vision.

To date the Drill Cover System has been used to treat 30,000 patients, in 50 hospitals across 15 LMICs. In all of their global markets, the company relies upon local distributors, with support from local staff on the ground. In addition, the company leverages partnerships with orthopaedic education and humanitarian organizations like the AO Alliance Foundation to create awareness of the product by supporting training activities globally. In order to support the most underserved communities Arbutus also works with groups like *Medecins Sans Frontieres* and Canadian Relief for Syria to introduce the Drill Cover System for conflict and disaster relief.

Evidence for use in the HIC markets is currently developing; this includes sales to the Canadian military, where feedback from field use has been very positive and plans are underway to possibly replace all existing surgical drills with the Arbutus products in the field. The company is also hoping to support a pilot use case in the UK, which is being planned by the Institute of Global Health Innovation (IGHI) and Imperial College Health Partners (IHP).

What are future prospects?

Whilst the innovation was initially conceived and developed for the needs of LMICs, it also provides an opportunity for hospitals in HIC to save money whilst still meeting institutional requirements. Given the financial pressures on healthcare providers in HICs, and the significant cost-saving potential, this may represent a more stable market for growth.

Future product improvements include an oscillating saw, cannulated drill and reamer functionality, and a quick coupling mechanism for numerous attachments. These incremental enhancements have been made to align closer with current surgical drill offerings in HICs. The company hope to launch the saw at the end of 2017 and the cannulated drill & reamer at the beginning of 2018.

What were / are the big challenges to making this successful?

Initially, the main challenge was in achieving regulatory approval, however, these hurdles have now mostly been overcome through investment in design, engineering and testing of products by third party evaluators. Beyond product development, for small start-ups like Arbutus, global marketing, securing distribution networks, and navigating procurement processes are some of the big challenges they face. Presently, the company is exploring the best sales strategy for increasing market share in LMICs. Procurement processes can be complex and opaque; as Arbutus Medical Inc. is restricted to sales through locally registered distributors in some contexts. Unfortunately, these distributors are more interested in selling

‘big-ticket’ items, where sales effort is less and margins can be greater, as compared with the necessary repeated sales of a low-cost item; such as the Arbutus Drill Cover System. Indeed, communication between distributors and hospitals can be poor, and evidence was found of bags being used beyond their lifespan, a potential patient safety risk, which is contrary to, and threatens Arbutus’s vision of increasing access to safer surgery. Furthermore, distributors are also not always interested in selling to the Tier 2 & 3 hospitals, where poorer patients are treated, and which Arbutus wants to reach, and so alignment of vision between the right distributor and the company is key.

In LMICs, Arbutus Medical Inc. faces intense competition from multiple other drilling solutions, these include hand drills, homemade but unsafe imitation drill covers, low-cost Chinese manufactured surgical drills, and donated Western surgical drills. In all hospitals visited evidence was found of offerings being used simultaneously and interchangeably. Proving cost-effectiveness versus low-cost Chinese manufactured drills is proving challenging, especially where quality standards for manufacturing processes and longer-term cost-savings are lower down the list of procurement prerequisites. Furthermore, once Arbutus becomes more widely known, it would not be surprising to see use of replicas in unprotected developing markets. To further compound the challenges, most recently incumbent manufacturers, such as Stryker, have begun to offer specific solutions for LMIC markets, though these offer a reduction of only about 30-50% compared to western offerings, while Arbutus product can offer up to a 94% reduction.

How were major challenges overcome?

Arbutus is working closely with distributors like Crown Healthcare Africa and leading global orthopaedics education organization AO Alliance Foundation to develop the best model for scaling. In India, the company founders are working with a range of organizations to develop market access strategies, including Intelicap and Sanrai International. The Arbutus team are supported through mentorship by a number of industry experts such as the senior management team of Edmonton-based medical device company priMED Medical Products, and the former Africa Director for Johnson & Johnson surgical sales who sits on the Arbutus Board.

There is also still need to address demand for economic evidence of cost saving especially against Chinese drills. One option could be to offer a subscription model with unlimited number of Drill Covers for a set monthly fee. A Chinese drill may last anywhere from 1-3 years based on quality and may cost as little as \$1500 (£1200); a subscription model would need to compete both in cost and lifespan. However, such a model could avoid the danger of bags being over-used beyond the recommended number of cycles, resulting in patient safety and brand risk.

How is impact evaluated?

Impact is projected based upon estimated number of surgeries performed with the Arbutus Drill Cover System from client hospital facilities. At specific sites the company is trying to

measure more complex clinical and socioeconomic indicators; work is on-going. Laboratory tests have examined drilling time; drilling accuracy; plunge depth, weight & size; drill speed and torque. Reputable external laboratories have undertaken in-depth electrical safety and hydrostatic pressure testing for barrier performance, as well as comprehensive cleaning and sterilization validation. A full list of tests is shown in table 1.

Currently, limited data is available on clinical outcomes as compared to alternative drilling methods; however there have been no reported adverse events over the course of more than 30,000 cases performed with the Drill Cover System. Nevertheless, the Drill Cover System meets all required standards for use in the UK, and clinical outcome data is only needed as part of a post-market analysis.

DISCUSSION

Does the UK need this innovation? With the NHS under pressure to save £22 billion by 2020, any little or significant cost savings can contribute towards that goal. We have explored this one specific frugal innovation to evaluate prospects savings it affords. At £10 billion, musculoskeletal disease has the third largest budget and already accounts for over 25% of surgical interventions within the NHS [4]. The Arbutus Drill Cover System presents a viable, regulatory approved alternative, which is much cheaper than mainstream commercial offerings generally considered in procurement. The UK is estimated to have 5,000 surgical drills that each cost around £23,000, which is a major and critical component needed in orthopaedic surgeries. The Arbutus Drill Cover System costs around £1500. As shown above, depending on whether a comparative assessment is done for one hospital or for all of the NHS, and whether it is done for upfront costs or total costs incurred for a period of five years, potential savings range from 85% to 94%.

According to anecdotal evidence from surgeons working in the NHS, some of the drills currently being used are not fulfilling their expectations. Drills are often out-dated and will soon need replacement. The more likely and only current option is to procure exorbitantly expensive clinical drills. Incumbent offerings involve autoclaving the whole drill along with the battery, a long established practice and one that is only now beginning to be challenged out of necessity of unaffordability in low income settings and increasing pressures for savings in high income settings. The alternative practice of only autoclaving the cover could deliver a cost reduction. And quality of care would be unchanged but at a fraction of the cost.

Hospitals are typically equipped with many contemporary and expensive drills because turn-around time can be long for sterilization of equipment, which is typically done offsite. The Arbutus system requires fewer drills, whether surgical or hardware ones, as only the cover needs to be swapped and sent off for sterilization after each surgery. Given there are many expensive drills already in use, to make the transition smoother from the old to the new, the lifespan of existing surgical drills can be prolonged as fewer are needed and the drill and battery itself does not need to be sterilized after each surgery.

Evidence of use in the Western markets is currently developing; this will make it easier to sell the device in the UK, Canada and US. This includes sales to the Canadian military, where feedback has been very positive and plans are underway to possibly replace all existing surgical drills with the Arbutus products in the field. As well, Arbutus is currently launching a pilot at the 4 largest teaching hospitals in Johannesburg, South Africa, with clinical champions bought in. Similar pilots are being planned in Canada and the US. Finally, the company is also supportive of facilitating a pilot use case in the NHS, which is being planned by the Institute of Global Health Innovation (IGHI) and Imperial College Health Partners (ICHP).

IGHI and ICHP are working closely with Arbutus to build the use and business case for NHS to consider adopting this innovation through a pilot study at major London hospitals. Arbutus is supportive of this pilot and is ready to back its product offering with warranty and replacement guarantees. Drills are covered by a 2-year manufacturer's warranty. Arbutus Drill Cover Linens are covered for 75 cycles given normal use conditions. Arbutus Drill Cover Chucks and Adapters are covered by a 1-year Arbutus warranty. As a positive show of confidence and support, and to help de-risk the initial use case, the company is willing to consider a partial refund, rebate, or free replacements if actual use case scenario significantly differs from the predicted model.

The technology offering as an innovation cannot be considered without carrying out due diligence on the type of organisation backing it, its capacity to scale up, and meet the requirements of large health systems. The company is backed by impact investors and venture capital funds like Grand Challenges Canada. The company is run by a team of dedicated bioengineers and social entrepreneurs, who are supported by reputable mentors. The company has partnered with the AO Alliance Foundation, one of the leading orthopaedic education institutions and has secured professional champions in several frontline and major public, private, and NGO-based hospitals who are using it and providing crucial user feedback for further development of the offering. However most of these are frontline surgeons (see for instance article in the Guardian [13]), and while they are important to secure buy-in for use in the theatre, Arbutus probably needs to extend its list of innovation champions to procurement decision-makers.

The innovation journey from bench to bedside is fraught with challenges and risks. Some potential challenges to wide scale adoption that need to be considered by any organisation seeking to pilot this for use in high income countries include:

1. In LMICs, incumbent companies are already giving away reconditioned drills in target market areas of the Arbutus drill. They are also coming up with less costly alternative models (e.g. Stryker System G). Low cost Chinese competitors are also available and range from \$800 to \$3,000, but vary significantly in quality.
2. In the NHS, behavioural reticence and cognitive bias could render uptake of Arbutus Drill Cover a slow process [14,15]. But these can be overcome with client education and evidence of safety and efficacy as well as through directives from management in favour of cost efficiency savings.

3. As the Drill Cover needs to be replaced after 75 cycles, NHS procurement decision makers need to be convinced of overall system wide cost savings beyond just the initial capital outlay. This system analysis is underway between IGHI, ICHP, Arbutus and pilot test sites.
4. While the parties involved in this study have attempted to carry out preliminary due diligence on the supplier in so far as proposing and planning pilot use cases, the full due diligence activity for wide scale adoption is best carried out by the procurement departments negotiating the full deal.

We have presented here the prospects of potentially significant cost savings from one specific frugal innovation. At the same time we caution against relying too much on one product for wide scale savings across a large health system. But our argument here is that such consideration for testing and implementation needs to be taken piece meal, step-by-step, and meticulously through small but several pilot tests. Such efforts when taken together, can offer significant savings across the system. And this is only possible if we embrace cultural change and create openness among health systems to innovations from unusual sources and that involve unorthodox practices which challenge long held practices.

CONCLUSIONS

As a frugal innovation, the Arbutus Drill Cover medical device holds much promise in reducing upfront and lifespan costs for one of the most fundamental equipment to the practice of orthopaedic surgery without any loss of effectiveness or safety benchmarks. The innovation has gone through rigorous internal and third party evaluations for medical devices. However, if the NHS is to realise the significant cost-saving potential of Arbutus Drill Cover System, the innovation will need support to navigate the complicated and decentralized procurement processes of such a large health system, and clinicians and healthcare leaders will need to overcome cognitive bias against an innovation deemed to be untraditional.

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Competing interests:

Readers may rightfully conclude that the rationale for the paper was to promote the device discussed. But the authors declare they have no competing interests in the innovation. Rather the authors seek to use the Arbutus Drill Cover System as an exemplar of the challenges faced by innovations conceived in LMIC, and by entrepreneurs and innovators, as they seek to spread innovations within High Income Countries.

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SUPPLEMENTARY DATA (Videos, Figures, Tables)

Video File 1: Arbutus Medical Product Portfolio

Video File 2: DrillCover System Loading Instructions

Figure 1: Arbutus Medical Drill Cover fully sealed with DeWalt drill beside.

Figure 2: Arbutus Medical Drill Cover System disconnected to show chuck mechanism and linen, with DeWalt drill beside.

Figure 3: Drill Cover System being assembled.

Figure 4: Close-up of the Drill Cover System, specifically highlighting fully sealed waterproof chuck interface.

Figure 5: Oscillating saw launching towards the end of 2017. Product will feature a quick-change cam mechanism for easily switching blades (not shown here)

Figure 6: Cannulated drill and reamer launching early 2018. This features a universal quick-change interface for easy exchange of AO, Jacobs, Hudson, and K-wire collet during practice.

Table 1: Evaluations completed on the product

1. Hydrostatic Pressure Testing for Barrier Performance:	Barrier performance evaluation for all critical zones within metal and linen components of product, using pressurized testing with simulated blood.
2. Biological Evaluation	Cytotoxicity testing, chemical composition of constituent materials, effects of manufacturing processes, effects of interaction between materials and contact with patient, material degradation and leachable substances.
3. Usability and Human Factors Evaluation	Formal usability and human factors evaluation completed with nurses and surgeons to ensure ease of use while maintaining sterility, as well as validation of labelling and training materials.
4. Lifetime Testing	Extensive lifetime and durability testing in high-fidelity simulated use environments to ensure linens and other components withstand the demands of in-field use.
5. Electrical Evaluation	Third party lab evaluations with QAI Labs to show electromagnetic compatibility, electromagnetic interference, and leakage in line with EMI requirements for medical devices.
6. Drill In-field Use and Warranty Data	Analysis of warranty claims from Bosch and DeWalt over hundreds of thousands of drill devices in the field confirm electrical risk analysis results and

	safety.
7. Drill Performance Studies	Evaluations to ensure appropriate drill speed, torque, pull-out strength, and over-heating performance.
8. Bone Drilling Performance Study	Evaluation of surgical drill and Arbutus Drill Cover System drilling into bone models by surgeons showed no statistically significant difference in hole size, accuracy, usability, or time.
9. Steam Sterilization and Cleaning Validation	External lab testing with Nelson Laboratories to confirm and validate effectiveness of steam sterilization protocol and instructions.
10. Clinical Study	Clinical evaluation focused on usability showed preference over manual hand drills across 95 orthopaedic cases, showing a 30 minute reduction time per case over manual drills.
11. Packaging Performance Evaluation	Verifies packaging performance for safety of shipping and storage.
12. ISO 13485 Certified Quality Management System	All Arbutus products are designed, manufactured, stored, and marketed under a carefully controlled ISO 13485 QMS as certified by BSI.
13. Comprehensive ISO 14971 Risk Management File	Arbutus Medical follows a rigorous ISO 14971 Risk Management process for ensuring safety and efficacy of all products.

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