Exploring the role of Design in the context of Medical Device Innovation

DUNN Jessica Lea; KO Keum Hee Kimmi*; LAHOUD David; NUSEM Erez; STRAKER Karla; and WRIGLEY Cara
School of Architecture, Design and Planning, The University of Sydney, Sydney, Australia
* corresponding author e-mail: kimmi.ko@sydney.edu.au

Technology is the leading driving force in healthcare and medical device design, however, innovations which emerge from these practices are often driven by clinical requirements. Such innovations are focused on developing products that addresses current health issues, diseases or medical problems – often lacking consideration of the end users’ needs. Design innovation advocates that user-centred design happens much earlier in the product development process so that the patient needs are prioritised. However, this emerging field is yet to be defined and explored in a medical context. This paper therefore proposes a framework of Medical Device Design Innovation to explore the role of design in medical device innovation through two medical device case studies. The proposed framework suggests a way to navigate the nuances and complexities of the medical device industry in order to put the patient first while ensuring commercial viability.

Keywords: Medical device design, patient centred design, design innovation, ventricular assist devices, ankle-foot orthoses

Introduction

Medical device manufacturers create life-changing innovations through the collaborative expertise of various disciplines including engineering, manufacturing, clinical, regulatory, marketing, sales and business specialists. The role of the designer is often that of user advocate (Privitera, Southee, & Evans, 2015). However, the design team may also be responsible for aesthetic design, form giving, human factors application and testing, along with implementing contextual inquiry and/or ethnography methods (Petrie & Copeland, 2011; Privitera, 2017). Appropriate use of design tools and methods ensures that the user experience is championed from the early stages of product development and continues throughout the product development process as design trade-offs need to be made (Norman, 1986).

While cutting-edge technology advancement in medical device design is absolutely vital, it is the overall experience (cognitive and emotional) which impacts on the daily life of the patient and caregiver (Bate & Robert, 2006). Exemplary medical device design integrates technology development with user needs (Martin & Barnett, 2012). According to Martin and Barnett (2012), medical device manufacturers are motivated to conduct user research for regulatory compliance during the product development process. Both the European Union and the US Food and Drug Administration (FDA) require that human factors engineering processes be followed and standards be met, demonstrating that ergonomics, human factors, or user-centred design have been considered (International Organization for Standardization, 2015; Martin & Barnett, 2012). Similarly, funding for medical research requires technology developers to prove relevance to ‘users’ or ‘stakeholders’ for the healthcare research funding decision process (Martin & Barnett, 2012). Human-centred design should be central to all medical device development to ensure that user needs are met. However, user involvement

This work is licensed under a Creative Commons Attribution-NonCommercial-Share Alike 4.0 International License.
https://creativecommons.org/licenses/by-nc-sa/4.0/
often comes later in the product development process, when the form and function has already been determined, and the ability to innovate based on user needs is limited due to a number of fixed parameters (Throckmorton, Patel-Raman, Fox, & Bass, 2016). The technological aspects of product development are often separated from the user aspects or only function to determine product appearance (Jones, 2013; Martin & Barnett, 2012). Schaeffer (2012) describes the role of human factors in this process as “prevention through design”, to minimise risk by preventing human error, adverse events, and product recall.

Design innovation advocates that user-centred design happens much earlier in the product development process so that patient needs are prioritised. It is anticipated that the participatory methods used in design could tap into the tacit knowledge of stakeholders (i.e., practitioners, patients and caregivers) and identify their latent needs. This paper therefore explores the role of design in ensuring that patient needs become a point of focus in the development of medical devices, with the aim of improving the patient experience. To understand how the design innovation model could be applied specifically to the challenging field of medical device innovation, the Medical Device Design Innovation framework is presented and explored through two medical device case studies, including: Ankle-Foot Orthoses (Class I); and Ventricular Assist Devices (Class III). The proposed framework suggests a way to navigate the nuances and complexities of the medical device industry in order to put patients first whilst also ensuring commercial viability.

**Literature Review**

**The Complexity of Medical Device Design**

Designing a medical device is exponentially more complicated than designing a consumer product (such as a new cutlery set or even an electric toothbrush), and thus traditional definitions of design-driven innovation (Verganti, 2009) may appear naive and oversimplified when overlaid into this field. Many medical devices are not simply distributed or sold direct-to-consumer or the end-user, which is especially true for devices Class II and above. A number of conflicting considerations mean that desirable product aesthetics and meaning-making are much more complex to attempt – often requiring significant compromise. Among others, these considerations include: uncertainty, regulatory environment, complicated diagnostic pathways, complex payment models, biocompatibility of materials and patient compliance (Hanna, Manning, Bouxsein, & Pope, 2001; Hunink et al., 2014; Kucklick, 2013; Lynch et al., 2015; Narayan, 2012; Wimms, Richards, & Benjafield, 2013). Additionally, all medical devices, if sold in the US, must conform to detailed FDA General Regulatory Controls.

Much of the literature on medical device design or innovation stems from the field of engineering, e.g., the work of Ogrodnik (2012). Subsequently, technology is the leading driving force in healthcare and medical device design (Thimbleby, 2013). There is a gap in the research for understanding how innovation driven by design (i.e. design innovation) can be used to address the needs of users holistically in a way that generates value for a diverse range of stakeholders. Such stakeholders are limited not only to patients who receive clinical treatment with medical devices, but also medical device manufacturers, insurance companies, governments, regulatory agencies, healthcare providers, hospitals, clinicians, healthcare practitioners, surgeons, home medical equipment providers and patient caregivers. This gap becomes more pertinent to address due to the notion that medical devices must, in some way, interface, interfere and intervene with the human body (U.S. Food and Drug Administration, 2018). Thus, the risk of mechanical, electrical, system or technical failure is more critical than that of a standard consumer product, justifying the need for a strict regulatory environment which strongly influences when and how innovation is able to occur. However, it cannot be denied that a blurring of the boundary between consumer and medical products has taken place in recent years (Shinbane & Saxon, 2016). In the modern era we live in, patients expect their medical devices to operate and function as well as (if not better than) the consumer products they interact with on a daily basis (Nilsson & Sheppard, 2018). Thus, there is increasing interest in testing consumer innovation models for their applicability to more highly-regulated and high-risk industries such as medical device product development.

**Medical Device Classes, Risk, Complexity and Design Innovation**

For this paper, we refer to the three classes of medical devices according to the FDA classification system (see Table 1), since the US is one of the biggest market influencers in medical device product development. However, the authors recognise the scope of classifications for medical devices across different regions.
Table 1: The three classes of medical devices according to the U.S. Food and Drug Administration (BMP Medical, 2018; Sikorski, 2019; U.S. Food and Drug Administration, 2019a; White, 2018) and FDA Regulatory Requirements for Medical Devices before release onto the US market (U.S. Food and Drug Administration, 2018e, 2018d, 2018c, 2018b)

| Class   | Risk            | Description                                                                 | Examples                                                                 | FDA Regulatory Requirements |
|---------|-----------------|----------------------------------------------------------------------------|------------------------------------------------------------------------|----------------------------|
| Class I | Low to Moderate | Devices are common, everyday medical devices, involving less sustained contact with a patient, and are generally would not in contact with internal organs. Majority of devices are either exempt from the regulatory process or subject to the minor regulatory requirements. Class I devices present a low barrier and are straightforward to bring to market – yet are still subject to FDA General Controls which constitute a series of standards for all medical devices. | Ankle-Foot Orthoses, Tongue Depressors, Enema Kits, Elastic Bandages, Exam Gloves, Surgical Caps, Crutches, Slings, Mechanical Wheelchairs, Toothbrushes, Dental Floss, Stethoscopes, Forceps, Nasal Dilators, Hearing Aids, Bedpans, Device Accessories (e.g. Cleaning Brushes) | General Controls, i.e.:  
- Adulteration  
- Misbranding  
- Device registration and listing  
- Banned devices  
- Notification and repair, replacement, and refund  
- Records and reports  
- Restricted devices  
- Good Manufacturing Practice  
And, if new and novel: Premarket Approval (PMA) or if PMA exemption can be proven; 510(k) – Premarket Notification showing substantial equivalence |
| Class II | Moderate to High | Devices may be diagnostic or come into contact with a patient’s internal organs. In addition to General Controls, Class II devices are also subject to Special Controls due to the added complications involved in providing reasonable assurance of the safety and effectiveness of such devices. Class II devices also undergo the FDA’s Premarket Notification 510(k) process to justify the device’s equivalence to another device that has already been legally marketed, thus demonstrating safety and effectiveness. | Surgical Meshes, Condoms, Hypodermic Needles, Acupuncture Needles, Neonatal Incubators, Catheters, Blood Pressure Cuffs, Powered Wheelchairs, Infusion Pumps, Blood Transfusion Kits, Vacuum Regulators, Wheeled Stretchers, Breast Pumps, Pregnancy Testing Kits, Electrocardiograph (ECG) Machines | General Controls; 510(k) – Premarket Notification showing substantial equivalence plus device-specific Special Controls:  
- Performance standards  
- Postmarket surveillance  
- Patient registries  
- Special labelling requirements  
- Premarket data requirements  
- Guidelines |
| Class III | High           | Devices in this category support or sustain life, are implanted, or exhibit potential significant risk of injury or illness. Novel devices and unproven technologies also fall under this classification. In addition to the other regulatory controls, Class III devices must also undergo the FDA Premarket Approval (PMA) process to prove safety and effectiveness – involving a rigorous scientific study requiring clinical trials, unless an exemption can be proven. | Ventricular Assist Devices, Pacemakers, Defibrillators, High-Frequency Ventilators, Aortic Stents, HIV Tests, HPV Detection Kits, Replacement Heart Valves, Neurosurgical Lasers, Intrauterine Contraceptive Devices (IUDs), Cochlear Implants, Foetal PH Monitors, Implanted Stimulators (for people with Parkinson’s disease), Implanted Prosthesis | General Controls; plus Premarket Approval (PMA) including:  
- Technical data  
- Non-clinical laboratory studies data  
- Clinical investigations data  
Or, if PMA exempt can be proven; 510(k) – Premarket Notification showing substantial equivalence |
The major distinguishing factor between medical device classes is risk (BMP Medical, 2018). Increased design complexity correlates with increased risk (Figure 1). Class I and Class II devices are characterised by a lower barrier to entry and a reduced risk (University of Limerick School of Design, 2019). Thus, design and design innovation are being explored and showing prevalence in the domains of Class I and II medical devices due to this reduced risk and lower barrier to entry (University of Limerick School of Design, 2019). It has been shown that a design innovation approach can lead to highly-successful outcomes for design interventions based upon deep customer insight for lower-risk industries such as consumer electronics, travel, and fashion retail (Wrigley & Straker, 2018), and is also beneficial applied to social innovation projects (Haines-Gadd et al., 2015). Similarly, lower-risk classes of medical devices such as healthcare diagnostics lend themselves well to a design innovation approach (Kyllin & Gardien, 2009). Nevertheless, there is a paucity of data regarding the use of design innovation in field of high-risk Class III medical devices (see Figure 1). Due to the higher barrier to entry and increased risk, little is known about the value of design innovation in Class III medical devices. This is unfortunate, as an approach which considers the needs of patients (rather than purely technology) at the onset of design can have significant ramifications for patients' quality of life. It is understandable that this proposition might encounter industry resistance since proper user research and successfully integrated user-centred design may result in challenging the entire fundamental concept behind a medical device (Martin & Barnett, 2012).

Figure 1: Three classes of Medical Devices correspond to increased risk and increased design complexity (including the human factors, service and system). An opportunity for Design Innovation to move into Class III medical devices exists. Adapted from University of Limerick School of Design (2019)
Introducing the Medical Devices Design Innovation Framework

According to design thinking principles, innovation occurs at the intersection of human desirability, technical feasibility, and business viability (Brown, 2009; IDEO, 2019). When lifted to the strategic level, according to design-led innovation principles, an innovative design outcome results when technology (i.e. the core intellectual property) addresses user needs through human-centred design and also disrupts the existing business model with a strategic value offering (Bucolo, Wrigley, & Matthews, 2012; Wrigley, 2017, p.236). Building on both the design thinking model and the design-led innovation model (see Figure 2), here the authors introduce the Medical Device Design Innovation (MDDI) framework (see Figure 3).

Figure 2: The Design Thinking model on the left (Brown, 2009; IDEO, 2019) and the Design-Led Innovation model (Bucolo et al., 2012; Wrigley, 2017) on the right, adapted from Wrigley (2017, p.236)

Figure 3: Design Innovation Framework for Medical Devices
The MDDI conceptual model has also been inspired by the authors’ understanding of Product Service Systems (PSS) (Manzini & Vezzoli, 2003; Tukker, 2004, 2015; Wallin, Parida, & Isaksson, 2015). Each of the segments in the framework corresponds to a key element of a proposed design innovation approach as it applies specifically to the design and development of medical devices within the context of a highly complex field. The MDDI model provides a conceptual map for each of the key factors that must be considered at the scoping phase and throughout the development process for an innovative design-led intervention within the field of medical devices. Careful consideration of each segment ensures that requirements for design innovation can be met. The order of exploring each segment is not critical, but all must be examined in depth at the early stages of design to inform the design innovation process and to successfully apply the model.

**Emotional – Desirability (People)**

Understanding and meeting users’ emotional needs is the core value of this segment, achieved through eliciting deep customer insights and then designing for them. The holistic user experience of a medical device is integral to the Emotional segment of the framework. Here, latent user needs can be addressed through stakeholder engagement and human-centred design research methods that are directed at discovering tacit knowledge and users’ key emotional needs. Here, we ask: who are the key users? Are we solving the right pain points for each of the key users (whether directly or indirectly involved)? Indirectly involved stakeholders’ needs might influence the outcome of design. This segment situates design aesthetics, industrial design, user experience design, and interactions, and how user groups experience a medical device through a series of touchpoints throughout their treatment journey. Opportunities are identified here to design emotional user experiences via new products, services and systems that are driven by desirability.

**Functional – Feasibility (Technology)**

The core intellectual property – i.e., the functional foundation of how a device works to successfully provide disease treatment resides in this segment. Feasibility is borne of appropriate selection and implementation of technology. Technological development represents the ability to manifest a desired user experience through both physical and digital means. Technology development represents the greatest potential for risk due to factors such as manufacturing process constraints, cost drivers, or biocompatibility of materials, but is also currently the most significant industry driver in medical devices. However, in this framework, technology must be reframed as an enabler of user experience rather than a singular driver of innovation potential. Technological advances fall under the Functional segment, where it is essential to determine whether the technology currently exists to accomplish what users genuinely need. If not, whether the technology can be feasibly developed within a reasonable cost and timeframe needs to be determined. Here, we build on the strengths of current and core operational capabilities.

**Structural – Viability (Business)**

The Structural segment encompasses the wider ecosystem of manufacturers, insurance companies, governments and healthcare providers (such as hospitals). The medical device regulatory environment and FDA requirements (the ‘ticket to play’ in the Medical Devices industry) are also situated into a stakeholder structure within this segment and herein lies the economic value and value chain delivered by medical devices. Building globally competitive, viable and sustainable business models is imperative, whilst balancing the complex ecosystem of stakeholders (i.e. customers and payors), which collectively form a piece of the structural puzzle. In this segment, it is necessary to consider both the long-term and short-term horizons of growth. This segment is responsible for building the infrastructure to support the holistic user experience of a medical device, and the services and systems that resolve their needs.

**Human Factors (Functional + Emotional)**

This segment of the MDDI framework encompasses an understanding of human behaviour interactions involved with product experience both directly (tangible) and indirectly (intangible). The goal of this segment is to enhance both physical and emotional user experience through embodiment, interactivity and communication. Through human factors, optimum usability is created when both physical and psychological human capability and limitations are designed into the user experience, hence the importance of achieving an understanding of the holistic user experience when designing any product, but especially medical devices.

Evans and Geiselhart (2012) identified a number of usability factors which may influence an individual’s product experience that should be considered when designing medical devices and their associated systems,
including: (1) physical abilities, i.e., anthropometry, biomechanics and sensory abilities; (2) cognitive abilities, i.e., how the brain processes information and learn new things, memory, and habits; (3) state of being, i.e., the general health of users, disease states and comorbidities that challenge patients’ mental and emotional states, and motivation for learning new things; and (4) experiences, i.e., educational backgrounds, and skills that will guide behavioural interactions. Moreover, environmental factors such as physical environment and life circumstances need to be considered as these encourage or discourage usability and influence overall user experiences.

**Service (Emotional + Structural)**

The service segment is intended to provide an intangible service in order to fulfil specific customer or user needs through an intertwined web of stakeholder groups and user touch points throughout the treatment journey, ensuring device users are consistently engaged, educated, managed and supported. Patient experience improves more holistically through thoughtfully designed services which include disease treatment support and aims to reduce the burden of treatment as well as enhance the user experience throughout the patient journey. Here, we could explore better ways to recruit for clinical trials, explore ethics, determine candidacy for treatment and regulations that meet the altering requirements for the healthcare provider and government which in turn may add economic value through extended product lifespan and services. In this segment, marketing and sales channels may reside, as well as product lifecycle, replacement schedules and device maintenance, diagnostic pathways, and patient, practitioner and caregiver training and support.

**System (Structural + Functional)**

Medical device innovation encompasses many different sectors’ and stakeholders’ involvement. In addition, the ‘invisible’ underlying system that supports a commercially and clinically successful medical device may not be explicitly recognised for its significant contribution to innovation. The design influence of such invisible systems may not normally be prioritised. However, a well-considered system may support balancing the complexity of many different sectors’ and stakeholder’s needs and holistically sustain dialogues between these groups. Examples of the system include healthcare structures and strategies which may support building unique relationships with users. This, in turn, may enhance their loyalty and increase efficiency gains throughout the whole medical treatment life cycle by fulfilling stakeholders needs in an integrated and customised way. Consequently, the workload is reduced, and the value of a business is improved. In many cases, the system workflow is rendered invisible in the delivery of digital and physical products and services – the MDDI framework on the other hand, emphasises system workflow and makes it visible.

**Case Studies**

The Medical Device Design Innovation framework (see Figure 3) is explored further through two case studies representing the extremes in medical device classifications currently undertaking a design approach to innovation. These case studies include the Ankle-Foot Orthosis (AFO) and Ventricular Assist Device (VAD), which are Class I and III respectively.

**Case Study 1 – Ankle Foot Orthosis (AFO)**

Ankle-foot orthoses (AFOs) are thermoplastic braces that support the foot and ankle to compensate for weakness, correct deformities and improve walking ability. These devices are a highly effective non-surgical treatment for patients with walking difficulties, such as cerebral palsy (Wingstrand, Hägglund, & Rodby-Bousquet, 2014), inherited neuropathy (Scheffers, Hiller, Refshauge, & Burns, 2012), and brain and spinal cord injuries (Vogel, Mendoza, Schottler, Chlan, & Anderson, 2007). AFOs improve mobility, maintain surgical correction and prevent recurrence of deformities (Dickinson et al., 2007; Skaaret, Steen, Terjesen, & Holm, 2019). Like other Class I devices, such as bedpans and enema kits, AFOs have undergone minimal change in experiential design, focusing only on function development. The technology surrounding the field has continued evolving, but fabrication of the same designs using traditional, manually laborious, handcrafted methods has continued to proliferate in the field.

The project focuses on patient perspectives of AFOs and design innovation to facilitate the creation of patient-centric designs and improve the qualitative and experiential aspects of paediatric patient wellbeing. The need arises from the lack of AFO development beyond technical adjustments, and dissatisfaction elucidated by preliminary research into patient perspectives – highlighting opportunity for improvement not only in the functional aspects of the device, but also the experience surrounding it. The aim is to explore the process of
prescribing, producing, acquiring, and using an AFO to understand how the design and production of AFOs can be innovated to improve patient outcomes.

Figure 4: Design Innovation Framework for Ankle-Foot Orthoses

**Emotional – Desirability (People)**

Recognising the importance of emotional attachment and the capability of design innovation to promote patient-product connection is critical for long term treatment. AFO design considerations cannot be isolated to just those of the patient. Initial research suggests the value of indirect stakeholders (such as parents, carers and orthotic practitioners) in providing compelling insights into AFO design. The Emotional segment encompasses processes that will uncover experiential needs of all stakeholders, both active and latent. Human-centred approaches to design (emotional, aesthetic and functional) will generate novel and custom designs. In the context of a specific group of users - for example paediatric patients - this may foster greater attachment towards their AFO device through personalisation and comfort profiles. The manufacturing of such designs is feasible using additive manufacturing and a streamlined acquisition process.

**Functional – Feasibility (Technology)**

The primary technological shifts in the industry of AFOs surround the development of biometric analysis tools and similar testing facilities, but very little in the development of the AFO itself (Lai et al., 2010). Prior to the introduction and use of Polypropylene, development of AFO design spans from semi-permanent plaster casts to a metal and leather construction (Wronksi, 2019). Though polypropylene is now the industry standard, that technological shift continues with additive manufacturing. In the past 20 years additive manufacturing technologies (including 3D modelling software, 3D printers, materials and scanners) have emerged from technological infancy and present numerous advantages in manufacturing. Fortunately, the cost of this equipment has made public and private access financially less inhibitive (Wohlers & Gornet, 2014). Costs have reached a tipping point where price no longer inhibits procurement for both the orthotist/practitioners and the recipient patients, allowing for widespread adoption of this new process in lieu of the traditional methods of fabrication. Of the few relevant studies found investigating additive manufacturing in AFO development
(Cha et al., 2017; Faustini, Neptune, Crawford, & Stanhope, 2008; Jin, He, & Shih, 2016; Mavroidis et al., 2011) the overall design language and geometry of the AFO is merely replicated, showing little to no sign of innovation. A systematic review was conducted by Wojciechowski et al., (2019) and concluded similarly, that though additive manufacturing of AFO is being studied, it is an underdeveloped area lacking substantive research. This is unlike, for example, 3D printed bicycle frames, such as a stainless-steel bike produced by Tu Delft and MX3D, that demonstrate innovation in creating mesh-like designs that do away with a solid homogenous structure. Despite this, additive manufacturing capability and technologies are an apt tool that can be utilised through the design innovation approach, since the technology offers wide variation to accommodate many differing patient preferences identified in the study.

However, technological advances alone do not produce a set of design solutions. Through design innovation, open channels of collaboration, patient contribution and orthotist involvement can develop a new model for the AFO industry, community and businesses that operate within it.

**Structural – Viability (Business)**

The Structural segment positions the complexities of multiple stakeholders into a framework that balances and supports their competing priorities against the regulatory demands of governing medical authorities such as the FDA. This framework presents AFO practitioners, manufacturers, healthcare providers and insurance companies with Business as a conduit through which meaningful, life-changing and engaging products can be provided. Viable business structures are conceptualised resultant from research into novel payment models, profit structures and cost effectiveness. Innovative cost models generate avenues to innovative processes, for example additive manufacturing. The automated processes associated with additive manufacturing allow for a significant reduction in human labour hours, thus reducing operational costs in the long term, despite initial setup costs being higher i.e.: the purchase of a production grade 3D printer. Lower business costs result in lower costs to users, and decreased waiting time can increase patient satisfaction (corroborated by initial research). Timely AFO replacement increases clinical efficiency. This fosters a patient-centric business model. The adaptive nature of additive manufacturing also lends itself to the regulatory environment, with sudden changes to industry standards or regulations having less of a detrimental impact on manufacturing. Most anticipated changes can be accounted for with a material or geometry change.

**Human Factors (Functional + Emotional)**

Much of the literature surrounding AFO development, testing and use explores aspects of function, mechanical improvement, and biometric analysis with patients (Faustini et al., 2008; Lai et al., 2010; Lam, Leong, Li, Hu, & Lu, 2005; Ploeger et al., 2007). However, the MDDI model combines both Functional (technology) and Emotional (experience) factors of a product. The model identifies a void of substantial emotional experience qualitative data in the body of AFO research of AFOs. Design innovation highlights this deficiency as an opportunity for improvement of human factors and provides tools to remedy this. Initial research into patient perspectives of published literature and secondary data such online platforms (blogs, message boards, and support forums) form an extensive understanding of the opportunities associated the pragmatic and experiential aspects of using an AFO. Categorisation Matrixes and the use of qualitative data analysis software NVivo will transform the data points into thematic clusters. This is the basis for forming design recommendations and one of the methods utilised by design innovation (Joffe & Yardley, 2003)

**Service (Emotional + Structural)**

Service encapsulates the intangible experiences and circumstances surrounding a product and system. In the context of AFOs, the Service segment focuses on improving the procurement and acquisition process, appointment scheduling, professional training and communication between face-to-face interactions. This is of particularly importance in paediatric patients (whom initial research indicates may require up to 3 devices of increasing size per year during childhood, depending on growth). By directly addressing patient wellbeing as a priority, new spaces for product services are revealed. Utilising design innovation methods within this space could generate, for example, a patient-facing front end that could be a way that users could engage with and stay connected with their AFO, orthotist and a larger community of users. A combination of design with additive manufacturing technology can fulfil just that.
System (Structural + Functional)

Despite being a Class I medical device, the complexity of stakeholder experiences does not diminish. Preliminary research into qualitative patient feedback establishes a need for clear, ongoing relationships between the patients and all other stakeholders in the system. The desired value of the patient is an AFO that is delivered in a timely and accurate manner; a result that can be propagated by the inclusion of novel Structural approaches, (such as patient-centric business model) and, Functional approaches (such as additive manufacturing). A combination of these two aspects forms the System segment and can resolve many of the detractions present in the systems surrounding Class 1 devices.

Case Study 2 - Ventricular Assist Device (VAD)

A Ventricular Assist Device (VAD) is a mechanical pump that takes over the pumping function of the heart as an alternative treatment to transplantation for patients diagnosed with end-stage heart failure. VADs support patients while they are waiting for a future donor organ transplant (Bunzel, Laederach-Hofmann, Wieselthaler, Roethy, & Wolner, 2007; Jakovljevic et al., 2014) or when they are ineligible for transplant surgery (Boling, Hart, Okoli, & Halcomb, 2015; Jakovljevic et al., 2017; Kaan, Young, Cockell, & Mackay, 2010; Makdisi, Makdisi, & Bittner, 2017; McLarty, 2015; Prinzing et al., 2016; van Manen, 2017). The user experience of Ventricular Assist Devices is still far less than ideal, which in turn affects the patient’s, and their caregiver’s, quality of life (Friedman & McMahon, 2014; Kaan et al., 2010; Schlöglhofer & Schima, 2018). VADs place a number of limitations on their users (e.g., ordinary daily activities such as showering, exercising, driving and sleeping are impacted). In addition to the implanted VAD pump, there are a number of additional external wearable components that require constant monitoring and maintenance to ensure proper function, including the controller and external battery pack. These are connected to the pump via a driveline that extends from the internal VAD through an exit site on the patient’s abdomen. In addition to their overarching condition of heart failure all VAD patients have a risk of suffering from blood clotting, stroke, bleeding, infection, organ malfunction, device failure, and right heart failure (Schumer, Black, Monreal, & Slaughter, 2016; Starling, 2010) as a result of VAD treatment, which increases emotional impact on both patients and caregivers. While innovation through technology push and incremental market pull has been observed, the translation of deep user needs into innovative new user experiences is an emerging frontier in VADs.

Figure 5: Design Innovation Framework for Ventricular Assist Devices
Emotional – Desirability (People)

There are several key user groups (i.e. patients, caregivers and practitioners) to consider when designing for VAD treatment. In the Emotional segment, research will use a design innovation approach and practice to elicit authentic user stories of Ventricular Assist Devices in order to define the key needs of the three user groups above and translate, through design, these user desires into tangible and intangible innovations in the Human Factors, Service and System segments. This segment encompasses user-centred design, human-centred design, product form and function and emotional design, and may explore VAD digital channel interactivity and communication, or develop and use novel tools to determine emotional user experience of VADs.

Functional – Feasibility (Technology)

Currently the VAD industry is technology-development driven and engineering-centric. In the Functional segment, technology must be reframed as an enabler of innovation in VADs, not the driver. Regardless, the underlying technology of any VAD innovation must work with reliability and efficacy but does not necessarily have to be completely reinvented. Feasibility of both the physical equipment and a digital platform that includes any core technological expertise in the form of core intellectual property is situated in this segment. Future technology development for VADs should be prioritised according to deep insights on emotional user needs, instead of user needs being served on the basis of technology capabilities and limitations.

Structural – Viability (Business)

In the Structural segment, a viable business model for VAD manufacturers, insurance companies, government funding, and healthcare providers (including VAD hospitals) is considered imperative. Here, business is championed as an enabler of innovation that brings life-sustaining value to heart failure patients and their caregivers, through cost effectiveness, profit structures, and payment models involving e.g. research funding, government, Medicare, insurance companies, co-pay. This segment recognises and situates the weight of the medical device regulatory environment and FDA requirements into a stakeholder structure involving VAD manufacturers, VAD hospitals, research organizations etc. Alternative business and/or industry structures may be conceptualised in this segment.

Human Factors (Functional + Emotional)

In the existing literature on VADs, human factors and usability is addressed from an engineering perspective looking at componentry and features, how quality of life (QoL) can be impacted and why it is important, but so far there lacks a holistic thread to tie together the integration of technology (functional) with user experience (emotional) into an innovative application of human factors that drives radical innovation of these devices – design is well-placed to do this. Key authorities in usability and the intuitive use of VADs include Geidl et al. (2009, 2011), Granegger et al. (2016), Schima et al. (2014), Schlöglhofer & Schima (2018), and Throckmorton, Patel-Raman, Fox, & Bass (2016), however thus far, human factors is still considered quite late in the product development process. The research team proposes to use human factors principles to drive innovation by incorporating ‘Design for Wearability’ guidelines for wearable VAD equipment, and by improving communication and interactivity of a digital support channel.

Service (Emotional + Structural)

This segment situates services to support heart disease treatment and reduce treatment burden. It may encompass ways to improve the patient experience such as better clinical trial recruitment, more holistic view of the patient experience from a wellbeing lens, product delivered as a service (e.g. subscription to pump and peripherals, upgradability). This segment provides the space to consider ethical considerations, including device candidacy and Decision Support Tools (DSTs) and develop user-centred services such as dedicated digital channels/platforms and self-care support tools (Ko et al., 2018). Treatment pathways such as destination therapy vs. bridge-to-transplant, alternative business and service models, and propositions of shared value may be explored here.

System (Structural + Functional)

In the System segment there is a may be a need to simplify existing complexities that exist at the backend of VAD product development, regulation, marketing, technological device support systems, and to improve or create networks and interactivity between device (the technology) and the receiver of revenue (the business) in order to deliver the desired value to the customer and patient. This segment situates strategic healthcare
systems that may have implications for the broader scope of heart failure treatment pathways via healthcare strategies for hospitals and governments, for example.

**Medical Design Innovation Constraints**

The MDDI framework illustrates the applicability across the two extremes of Class I and Class III medical devices. The similarities include a need to meet general requirements of all medical devices. However, clear differences between a Class I and a Class III device arise in the increasing difficulty of translating a desirable user experience under immense technical complexity in the context of a more rigid structural environment with stacked constraints that must be navigated in order to achieve an innovative outcome.

Where design does play a role in the development of medical devices, the role is often pragmatic, business centric and/or inward facing – focusing on aspects such as cost-effectiveness (for the business), risk reduction, market placement and regulatory requirements (Medina, Kremer, & Wysk, 2013). An understanding of the role of design and need for design innovation in the field of medical device product development is scant in the wider academic literature, especially in the field of life-saving medical devices. Where design exists, there are many obstacles that distract from a user- or patient-centric innovation model. These obstacles have been attributed to the heavily restrictive influence of FDA requirements, reported as “the first external factor affecting a company’s ability to develop new medical technology and influencing a company’s product development priorities” (Medina et al., 2013). Such requirements exist for a compelling reason to protect patient safety and reduce the risk of adverse outcomes. Thus, design innovation faces unique requirements, constraints and challenges in the field of medical device design that are unlike any other in consumer product development. Herein lies the opportunity for the framework to yield its contribution (as detailed in Table 2).

**Table 2: FDA Regulatory Requirements for Medical Devices as they align to the Medical Devices Design Innovation framework – Class III includes requirements listed in Class I and II, Class II also includes all requirements listed in Class I**

|                      | Class I | Class II | Class III          |
|----------------------|---------|----------|-------------------|
| **EMOTIONAL** – Desirability (People) | --      | --       | Clinical investigations data |
| Human Factors (Functional + Emotional) | Records and reports | Postmarket surveillance | |
| **FUNCTIONAL** – Feasibility (Technology) | Good Manufacturing Practices | Performance standards | Technical data Non-clinical laboratory studies data |
| Service (Emotional + Structural) | Notification and repair, replacement, and refund | Patient registries | -- |
| **STRUCTURAL** – Viability (Business) | Device registration and listing | Special labelling requirements | Premarket Approval (PMA); or, if exempt: 510(k) – Premarket Notification showing substantial equivalence 510(k) – Premarket Notification showing substantial equivalence |
| System (Structural + Functional) | Adulteration Misbranding Banned devices Restricted devices | Guidelines Premarket data requirements | -- |
Conclusion

This study explores the role of design in medical device innovation and introduces the MMDI framework as a way to innovate in medical device product development through using a design innovation approach that has been proven successful in other industries. Two case studies are detailed, with the findings presented suggesting that the MDDI framework is applicable to the wide range of medical devices available from Class I through to Class III. While this study does not offer a conclusive answer to the question of how a design innovation approach can be best applied to medical device product development to guarantee innovation, it does suggest a new way to navigate the nuances and complexities of the medical device industry from early-end device development through to product launch, in order to better balance user needs with commercial viability.

It is possible, in exploring the Medical Device Design Innovation framework, that learnings could be extrapolated to the wider field of healthcare or health services design that are intrinsically interconnected with medical devices or rely on medical devices to supply care, in order to identify new opportunities for innovation. One example might be for surgical training tools, which exist in the medical education field but may not necessarily be classified as medical devices. The authors acknowledge the shortcomings of this publication in that the Medical Device Design Innovation framework has been exemplified and tested on only two case studies, and this does not yet allow us to validate the model in the vastness and variety of available medical devices.

The Medical Device Design Innovation framework is conceptual in nature and thus requires further exploration in future studies. From the perspective of the VAD and AFO case studies, future research will test the Medical Device Design Innovation framework as a catalyst for driving design innovation in each of these two devices. The framework will be used to assess how novel design proposals for each of these devices fit into a wider innovation context for medical devices in general. Further research is also needed to compare the official FDA Development Process (U.S. Food & Drug Administration, 2018a) to actual design-led innovation success stories whereby innovative ideas are nurtured from early-stage research through to product development, manufacture, launch, adoption, and hopefully widespread use and success in the marketplace. There currently exists insufficient research on non-designers who practice design in the field of medical device product development, and there is limited research on the role played by trained designers in medical device design – the work of Mary-Beth Privitera leads the way in this field (Privitera, 2015, 2017; Privitera et al., 2015; Weinger, Gardner-Bonneau, & Wiklund, 2011). Qualitative studies are needed to understand how medical device manufacturers are innovating by borrowing and adapting design methods tools, practices, and processes such as IDEO models (Kelley, 2016), design thinking, design-led innovation, agile, user-centred design, the double-diamond framework, UI/UX design, etc. and how designers are working in multidisciplinary, cross-functional teams. To make a stronger case for design innovation, there needs to be greater understanding from the field regarding how structural constraints (e.g. marketing, FDA requirements, or insurance reimbursement schemes) hinder innovation of medical devices. Research is needed that explores how traditional market research or 'Voice of the Customer' could be stifling innovation in medical device design by simply seeking to prove assumptions and not to deeply understand the relationship between the function of a device and the emotional experience of such a device; that is, asking customers what they want, rather than why they want it (Price, Wrigley, & Straker, 2015). Similarly, further research is needed to determine if and how the FDA 510(k) and similar processes worldwide could be inhibiting medical device innovation processes and endangering patients by making it easier for manufacturers to base a product’s design and safety case on a predicate product rather than create a novel invention that would require a PMA, significant investment, clinical trial before launch, and risk mitigation (Fargen et al., 2013). Additionally, research is needed on how the structural conditions of doing business with medical insurers may mean that manufacturers are incentivised to comply to existing insurance reimbursement codes based on older product configurations which also hampers innovation since better products don’t get made for patients because then those products wouldn’t be reimbursed, thus would not sell. Finally, the Medical Device Design Innovation framework could be tested in-house with a range of medical device manufacturers to further refine and improve upon the conceptual proposal.
References

Bate, P., & Robert, G. (2006). Experience-based design: from redesigning the system around the patient to co-designing services with the patient. *Qual Saf Health Care, 15*, 307–310. https://doi.org/10.1136/qshc.2005.016527

BMP Medical. (2018). What’s the Difference between a Class I Medical Device and a Class II? Retrieved February 1, 2019, from https://www.bmpmedical.com/blog/whats-difference-fda-medical-device-classes-2/

Boling, B., Hart, A., Okoli, C., & Halcomb, T. (2015). Use of Social Media as a Virtual Community and Support Group by Left Ventricular Assist Device (LVAD) Patients. *The VAD Journal: The Journal of Mechanical Assisted Circulation and Heart Failure, 1*, 1–15. http://dx.doi.org/10.13023/VAD.2015.15

Brown, T. (2009). *Change by Design: How Design Thinking Transforms Organizations and Inspires Innovation*. NY: Harper Business.

Bucolo, S., Wrigley, C., & Matthews, J. (2012). Gaps in Organizational Leadership: Linking Strategic and Operational Activities through Design-Led Propositions. *Design Management Journal, 7*(1), 18–28. https://doi.org/10.1111/j.1948-7177.2012.00030.x

Bunzel, B., Laederach-Hofmann, K., Wieselthaler, G., Roethy, W., & Wolner, E. (2007). Mechanical Circulatory Support as a Bridge to Heart Transplantation: What Remains? Long-term Emotional Sequelae in Patients and Spouses. *Journal of Heart and Lung Transplantation, 26*(4), 384–389. https://doi.org/10.1016/j.healun.2007.01.025

Cha, Y. H., Lee, K. H., Ryu, H. J., Joo, I. W., Seo, A., Kim, D.-H., & Kim, S. J. (2017). Ankle-Foot Orthosis Made by 3D Printing Technique and Automated Design Software. *Applied Bionics and Biomechanics, 2017*, 1–6. https://doi.org/10.1155/2017/9610468

Dickinson, H. O., Parkinson, K. N., Ravens-Sieberer, U., Schirripa, G., Thyen, U., Arnaud, C., … Colver, A. F. (2007). Self-reported quality of life of 8–12-year-old children with cerebral palsy: a cross-sectional European study. *The Lancet, 369*(9580), 2171–2178. https://doi.org/10.1016/S0140-6736(07)61013-7

Evans, C., & Geiselhart, E. (2012). Understanding the Patient Journey: A Human-Factors Road Map to Pharmaceutical Delivery Device Development. *BioProcess International, 10*(11).

Fargen, K. M., Frei, D., Fiorella, D., McDougall, C. G., Myers, P. M., Hirsch, J. A., & Mocco, J. (2013). The FDA approval process for medical devices: an inherently flawed system or a valuable pathway for innovation? *Journal of Neurointerventional Surgery, 5*(4), 269–75. https://doi.org/10.1136/neurintsurg-2012-010400

Fasntini, M. C., Neptune, R. R., Crawford, R. H., & Stanhope, S. J. (2008). Manufacture of Passive Dynamic Ankle-Foot Orthoses Using Selective Laser Sintering. *IEEE Transactions on Biomedical Engineering, 55*(2), 784–790. https://doi.org/10.1109/TBME.2007.912638

Friedman, E., & McMahon, M. (2014). TO VAD OR NOT TO VAD: That is the question. Improving the experience of receiving a Ventricular Assist Device (VAD). In *Proceedings of the International Symposium on Human Factors and Ergonomics in Health Care* (Vol. 3, pp. 238–245). SAGE Publications India: New Delhi, India. https://doi.org/10.1177/2327857914031039

Geidl, L., Deckert, Z., Zrunek, P., Gottardi, R., Sterz, F., Wieselthaler, G., & Schima, H. (2011). Intuitive use and usability of ventricular assist device peripheral components in simulated emergency conditions. *Artificial Organs, 35*(8), 773–780. https://doi.org/10.1111/j.1525-1594.2011.01330.x

Geidl, L., Zrunek, P., Deckert, Z., Zimpfer, D., Sandner, S., Wieselthaler, G., & Schima, H. (2009). Usability and safety of ventricular assist devices: Human factors and design aspects. *Artificial Organs, 33*(9), 691–695. https://doi.org/10.1111/j.1525-1594.2009.00844.x

Granegger, M., Schöglhofer, T., Ober, H., Zimpfer, D., Schima, H., & Moscato, F. (2016). Daily life activity in patients with left ventricular assist devices. *The International Journal of Artificial Organs, 39*(1), 22–27. https://doi.org/10.5301/iiao.5000464

Haines-Gadd, M., Hasegawa, A., Hooper, R., Huck, Q., Pabian, M., Portillo, C., … McBride, A. (2015). Cut the crap; design brief to pre-production in eight weeks: Rapid development of an urban emergency low-tech...
toilet for Oxfam. Design Studies, 40, 246–268. https://doi.org/10.1016/j.destud.2015.06.006

Hanna, K. E., Manning, F. J., Bouxsein, P., & Pope, A. (Eds.). (2001). Innovation and Invention in Medical Devices: Workshop Summary. Washington, D.C.: National Academy Press.

Hunink, M. G. M., Weinstein, M. C., Wittenberg, E., Drummond, M. F., Pliskin, J. S., Wong, J. B., & Glasziou, P. P. (2014). Managing uncertainty. In Decision Making in Health and Medicine (pp. 29–52). Cambridge: Cambridge University Press. https://doi.org/10.1017/CBO9781139506779.005

IDEO. (2019). Design Thinking: A Method for Creative Problem Solving. Retrieved April 16, 2019, from https://www.ideou.com/pages/design-thinking

International Organization for Standardization. (2015). IEC 62366-1:2015 - Medical devices -- Part 1: Application of usability engineering to medical devices. Retrieved from https://www.iso.org/standard/63179.html

Jakovljevic, D. G., McDiarmid, A., Hallsworth, K., Seferovic, P. M., Ninkovic, V. M., Parry, G., ... Macgowan, G. A. (2014). Effect of left ventricular assist device implantation and heart transplantation on habitual physical activity and quality of life. American Journal of Cardiology, 114(1), 88–93. https://doi.org/10.1016/j.amjcard.2014.04.008

Jakovljevic, D. G., Yacoub, M. H., Schueler, S., MacGowan, G. A., Velicki, L., Seferovic, P. M., ... Tan, L.-B. B. (2017). Left Ventricular Assist Device as a Bridge to Recovery for Patients With Advanced Heart Failure. Journal of the American College of Cardiology, 69(15), 1924–1933. https://doi.org/10.1016/j.jacc.2017.02.018

Jin, Y., He, Y., & Shih, A. (2016). Process Planning for the Fuse Deposition Modeling of Ankle-Foot-Othoses. Procedia CIRP, 42, 760–765. https://doi.org/10.1016/j.procir.2016.02.315

Joffe, H., & Yardley, L. (2003). Content and Thematic Analysis. In Research Methods for Clinical and Health Psychology (pp. 56–68). 1 Oliver’s Yard, 55 City Road, London England EC1Y 1SP United Kingdom: SAGE Publications, Ltd. https://doi.org/10.4135/9781849209793.n4

Jones, P. H. (2013). Design for Care: Innovating Healthcare Experience. Brooklyn, N.Y: Rosenfeld Media.

Kaan, A., Young, Q.-R., Cockell, S., & Mackay, M. (2010). Emotional Experiences of Caregivers of Patients with a Ventricular Assist Device. Progress in Transplantation, 20(2), 142–147. https://doi.org/10.1016/j.protrans.2010.02.008

Kelley, T. (2016). The Art Of Innovation Lessons in Creativity from IDEO, America’s Leading Design Firm. Profile Books.

Ko, K. H. K., Dunn, J. L., Straker, K., Nusem, E., Wrigley, C., & Gregory, S. (2018). A Comparative Content Analysis of Digital Channels for Ventricular Assist Device Patients, Caregivers, and Healthcare Practitioners. ASAIO Journal, 1. https://doi.org/10.1097/MAT.0000000000000924

Kucklick, T. R. (2013). The medical device R&D handbook. (Second). Boca Raton: CRC PressBoca.

Kyffin, S., & Gardien, P. (2009). Navigating the Innovation Matrix: An Approach to Design-led Innovation. International Journal of Design, 3(1), 57–69.

Lai, H.-J., Yu, C.-H., Kao, H.-C., Chen, W.-C., Chou, C.-W., & Cheng, C.-K. (2010). Ankle–foot simulator development for testing ankle–foot orthoses. Medical Engineering & Physics, 32(6), 623–629. https://doi.org/10.1016/J.MEDENGYPHY.2010.03.008

Lam, W. K., Leong, J. C. Y., Li, Y. H., Hu, Y., & Lu, W. W. (2005). Biomechanical and electromyographic evaluation of ankle foot orthosis and dynamic ankle foot orthosis in spastic cerebral palsy. Gait & Posture, 22(3), 189–197. https://doi.org/10.1016/J.GAITPOST.2004.09.011

Lynch, S., Blase, A., Wimms, A., Erikli, L., Benjafied, A., Kelly, C., & Willes, L. (2015). Retrospective descriptive study of CPAP adherence associated with use of the ResMed myAir application.

Makdisi, G., Makdisi, P. B., & Bittner, H. B. (2017). How to establish a successful destination therapy ventricular assist device program. Journal of Thoracic Disease, 9(4), 932–935. https://doi.org/10.21037/jtd.2017.03.139
Manzini, E., & Vezzoli, C. (2003). A strategic design approach to develop sustainable product service systems: examples taken from the ‘environmentally friendly innovation’ Italian prize. *Journal of Cleaner Production, 11*(8), 851–857. https://doi.org/10.1016/S0959-6526(02)00153-1

Martin, J., & Barnett, J. (2012). Integrating the results of user research into medical device development: insights from a case study. *BMC Medical Informatics and Decision Making, 12*(1), 74. https://doi.org/10.1186/1472-6947-12-74

Mavroidis, C., Ranky, R. G., Sivak, M. L., Patritti, B. L., DiPisa, J., Caddle, A., ... Bonato, P. (2011). Patient specific ankle-foot orthoses using rapid prototyping. *Journal of NeuroEngineering and Rehabilitation, 8*(1), 1. https://doi.org/10.1186/1743-0003-8-1

McLarty, A. (2015). Mechanical Circulatory Support and the Role of LVADs in Heart Failure Therapy. *Clinical Medicine Insights: Cardiology, 9*(Suppl 2), 1–5. https://doi.org/10.4137/CMC.s19694

Medina, L. A., Kremer, G. E. O., & Wysk, R. A. (2013). Supporting medical device development: a standard product design process model. *Journal of Engineering Design, 24*(2), 83–119. https://doi.org/10.1080/09544828.2012.676635

Narayan, R. J. (Ed.). (2012). *Volume 23: Materials for Medical Devices. ASM Handbook* (Vol. 23). Materials Park, Ohio.

Nilsson, T., & Sheppard, B. (2018). The changing face of medical-device design. Retrieved February 28, 2019, from https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/the-changing-face-of-medical-device-design

Norman, D. A. (1986). User centered system design: New Perspectives on Human-Computer Interaction. In D. A. Norman & S. W. Draper (Eds.), *User centered system design: New perspectives on human-computer interaction* (pp. 31–62). Hillsdale, New Jersey: Lawrence Erlbaum Associates, Publishers.

Ogrodnik, P. J. (2012). *Medical device design : innovation from concept to market*. Academic Press.

Petrie, A., & Copeland, D. (2011). The value of industrial design in medical device development. Retrieved October 31, 2017, from http://medicaldesign.com/prototyping/value-industrial-design-medical-device-development

Ploeger, H. E., Brehm, M. A., Bus, S. A., Nollet, F., Ridgewell, E., Rodda, J., ... Sangeux, M. (2007). Comparing the effect of a dorsal-leaf-spring AFO and a spring-hinged AFO on gait characteristics in plantarflexor weakness: A pilot study The effect of bilateral solid AFO on gait. *Arch Phys Med Rehabil, 36*, 6676. https://doi.org/10.1016/j.aphysrehab.2015.03.120

Price, R. A., Wrigley, C., & Straker, K. (2015). Not just what they want, but why they want it: Traditional market research to deep customer insights. *Qualitative Market Research: An International Journal, 18*(2), 230–248. https://doi.org/10.1108/QMR-03-2014-0024

Prinzing, A., Herold, U., Berkefeld, A., Krane, M., Lange, R., & Voss, B. (2016). Left ventricular assist devices-current state and perspectives. *Journal of Thoracic Disease, 8*(8), E660–E666. https://doi.org/10.21037/jtd.2016.07.13

Privitera, M. B. (2017). *Contextual Inquiry for Medical Device Design*.

Privitera, M. B. (2017). Designing Industrial Design in the Highly Regulated Medical Device Development Process. Defining our valuable contribution towards usability. *The Design Journal, 20*(sup1), S2190–S2206. https://doi.org/10.1080/14606925.2017.1352735

Privitera, M. B., Southey, D., & Evans, M. (2015). Collaborative Design Processes in Medical Device Development. *The Value of Design Research - European Academy of Design Conference*, (11), 1–12.

Schaeffer, N. E. (2012). The Role of Human Factors in the Design and Development of an Insulin Pump. *Journal of Diabetes Science and Technology, 6*(2), 260–264. https://doi.org/10.1177/193229681200600208

Scheffers, G., Hiller, C., Refshauge, K., & Burns, J. (2012). Prescription of foot and ankle orthoses for children with Charcot-Marie-Tooth disease: a review of the evidence. https://doi.org/10.1177/1743288X11Y.0000000052

Schima, H., Schlöghofer, T., zu Dohna, R., Drews, T., Morshuis, M., Roefe, D., ... Zimpfer, D. (2014). Usability of
ventricular assist devices in daily experience: A multicenter study. Artificial Organs, 38(9), 751–760. https://doi.org/10.1111/aor.12394

Schlöglhofer, T., & Schima, H. (2018). Wearable systems. In S. D. Gregory, M. C. Stevens, & J. F. Fraser (Eds.), Mechanical Circulatory and Respiratory Support (pp. 691–721). Elsevier. https://doi.org/10.1016/B978-0-12-810491-0.00022-9

Schumer, E. M., Black, M. C., Monreal, G., & Slaughter, M. S. (2016). Left ventricular assist devices: Current controversies and future directions. European Heart Journal, 37(46), 3434–3439b. https://doi.org/10.1093/eurheartj/ehv590

Shinbane, J. S., & Saxon, L. A. (2016). Digital monitoring and care: Virtual medicine. Trends in Cardiovascular Medicine, 26(8), 722–730. https://doi.org/10.1016/J.TCM.2016.05.007

Sikorski, M. (2019). The Difference between Class I, Class II and Class III Medical Devices. Retrieved February 4, 2019, from https://www.innovatum.com/2014/12/understanding-difference-class-ii-medical-devices/

Skaaret, I., Steen, H., Terjesen, T., & Holm, I. (2019). Impact of ankle-foot orthoses on gait 1 year after lower limb surgery in children with bilateral cerebral palsy. Prosthetics and Orthotics International, 43(1), 12–20. https://doi.org/10.1177/0309364618791615

Starling, R. C. (2010). Improved Quantity and Quality of Life: A Winning Combination to Treat Advanced Heart Failure*. Journal of the American College of Cardiology, 55(17), 1835–1836. https://doi.org/10.1016/J.JACC.2010.03.010

Thimbleby, H. (2013). Technology and the future of healthcare. Journal of Public Health Research, 2(3), e28. https://doi.org/10.4081/jphr.2013.e28

Throckmorton, A. L., Patel-Raman, S. M., Fox, C. S., & Bass, E. J. (2016). Beyond the VAD: Human Factors Engineering for Mechanically Assisted Circulation in the 21st Century. Artificial Organs, 40(6), 539–548. https://doi.org/10.1111/aor.12600

Tukker, A. (2004). Eight types of product–service system: eight ways to sustainability? Experiences from SusProNet. Business Strategy and the Environment, 13(4), 246–260. https://doi.org/10.1002/bse.414

Tukker, A. (2015). Product services for a resource-efficient and circular economy – a review. Journal of Cleaner Production, 97, 76–91. https://doi.org/10.1016/J.JCLEPRO.2013.11.049

U.S. Food and Drug Administration. (2018). Classify Your Medical Device - Is The Product A Medical Device? Retrieved April 16, 2019, from https://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm

U.S. Food & Drug Administration. (2018a). The Device Development Process. Retrieved February 1, 2019, from https://www.fda.gov/ForPatients/Approvals/Devices/default.htm

U.S. Food and Drug Administration. (2018b). Premarket Approval (PMA). Retrieved February 4, 2019, from https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketApprovalPMA/ucm2007514.htm

U.S. Food and Drug Administration. (2018c). Premarket Notification 510(k). Retrieved February 4, 2019, from https://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm

U.S. Food and Drug Administration. (2018d). Regulatory Controls. Retrieved February 4, 2019, from https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/default.htm#intro

U.S. Food and Drug Administration. (2018e). Regulatory Controls (Medical Devices) - General Controls for Medical Devices. Retrieved February 4, 2019, from https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/GeneralandSpecialControls/ucm055910.htm

U.S. Food and Drug Administration. (2019). Product Classification Database. Retrieved February 4, 2019, from
University of Limerick School of Design. (2019). Development of a Fuzzy Front End design framework to optimise commercial success of low risk medical device development. Retrieved February 3, 2019, from https://designfactors.ie/design-health/development-fuzzy-front-end-design-framework-optimise-commercial-success-low-risk

van Manen, M. A. (2017). The Ventricular Assist Device in the Life of the Child: A Phenomenological Pediatric Study. *Qualitative Health Research, 27*(6), 792–804. https://doi.org/10.1177/1049732317700853

Verganti, R. (2009). *Design-driven Innovation: Changing the Rules of Competition by Radically Innovating What Things Mean.* Boston, Massachusetts: Harvard Business Press.

Vogel, L. C., Mendoza, M. M., Schottler, J. C., Chlan, K. M., & Anderson, C. J. (2007). Ambulation in children and youth with spinal cord injuries. *The Journal of Spinal Cord Medicine, 30 Suppl 1*(Suppl 1), S158-64. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/17874702

Wallin, J., Parida, V., & Isaksson, O. (2015). Understanding product-service system innovation capabilities development for manufacturing companies. *Journal of Manufacturing Technology Management, 26*(5), 763–787. https://doi.org/10.1108/JMTM-05-2013-0055

Weinger, M. B. (Matthew B., Gardner-Bonneau, D., & Wiklund, M. E. (2011). *Handbook of human factors in medical device design.* CRC Press. Retrieved from https://books.google.com.au/books?hl=en&lr=&id=jAemLm2zu_oC&oi=fnd&pg=PP1&dq=MaryBethPri&sig=uCBe96856i16rcr3qqMr01HnQ1A#v=onepage&q=MaryBeth Privitera&f=false

White, S. (2018). What’s My FDA Medical Device Classification? Retrieved April 16, 2019, from https://cortex-design.com/blog/whats-my-fda-medical-device-classification/

Wimms, A. J., Richards, G. N., & Benjafield, A. V. (2013). Assessment of the impact on compliance of a new CPAP system in obstructive sleep apnea. *Sleep and Breathing, 17*(1), 69–76. https://doi.org/10.1007/s11325-012-0651-0

Wingstrand, M., Hägglund, G., & Rodby-Bousquet, E. (2014). Ankle-foot orthoses in children with cerebral palsy: a cross sectional population based study of 2200 children. *BMC Musculoskeletal Disorders, 15*(1), 327. https://doi.org/10.1186/1471-2474-15-327

Wohlers, T., & Gornet, T. (2014). *History of Additive Manufacturing.* Retrieved from http://www.wohlersassociates.com/history2014.pdf

Wojciechowski, E., Chang, A. Y., Balassone, D., Ford, J., Cheng, T. L., Little, D., ... Burns, J. (2019). Feasibility of designing, manufacturing and delivering 3D printed ankle-foot orthoses: a systematic review. *Journal of Foot and Ankle Research, 12*(1), 11. https://doi.org/10.1186/s13047-019-0321-6

Wrigley, C. (2017). Principles and practices of a design-led approach to innovation. *International Journal of Design Creativity and Innovation, 5*(3–4), 235–255. https://doi.org/10.1080/21650349.2017.1292152

Wrigley, C., & Straker, K. (2018). *Affected: Emotionally Engaging Customers in The Digital Age.*

Wronksi, S. (2019). History of the Orthotic devices. Retrieved February 5, 2019, from http://www.reh4mat.com/en/orc/history-of-the-orthotic-devices/
About the Authors:

Jessica Lea Dunn is an award-winning Industrial Designer with 7 years industry experience in research and technology development of patient interface products for the world’s leading tech-driven medical device company. She is also one of the most-followed people on Pinterest.

Keum Hee Kimmi Ko is an enthusiastic, dedicated designer and researcher with advanced knowledge in diverse design fields. She holds a Bachelor of Industrial Design (UNSW), Master of Design (UNSW, Politecnico di Milano) and Master of Philosophy by Research (UNSW).

David Lahoud is a product/industrial designer currently based at the University of Sydney where he is a research assistant, tutor and PhD candidate. He has a particular interest in CAD and additive manufacturing.

Dr Erez Nusem is an Associate Lecturer in Design Innovation for Health and Medicine. Through his research Dr Nusem is exploring the role of design in creating better outcomes and experiences for patients, doctors and other medical professionals.

Dr Karla Straker is an Early Career Development Fellow, in the Design Lab, located in the School of Architecture, Design and Planning, at the University of Sydney.

Dr Cara Wrigley is Professor of Design Innovation at The University of Sydney, residing in the Design Lab - an interdisciplinary research group within the School of Architecture, Design and Planning.