



Epoch Medical Innovations, Inc. is developing a family of advanced-sensing medical devices targeted to improve the mobility, comfort and quality of life for patients suffering from chronic venous diseases and lower limb amputation.

Company

We are an early stage company, formed in 2009, and located in Bellevue Washington. The company began by creating a fluid compression sleeve for treating deep vein thrombosis. The fundamental sensing and fluid management technology from this development was used to apply for and receive a Life Sciences Discovery Fund (LSDF) grant in 2013. The LSDF prototypes demonstrated the feasibility of an automated fluid bladder system for use in prosthetics to manage limb health and stability.

In 2016, Epoch Medical signed a Memorandum of Understanding (MOU) with an established prosthetics industry partner and evolved the design further for expanded user testing.

The Problem

Amputee residual limb size will increase and decrease throughout the day as the soft tissue is compressed during gait and fluid is forced out. The leg will also change volume over the course of months and years from long term muscular atrophy. Inconsistent fit of the prosthetic is the leading complaint of amputees and that problem can create skin breakdown and bruising. Amputees currently manage volume changes on an hour-by-hour and day-to-day basis by adding and removing socks (ply) to the residual limb when they feel discomfort. Exacerbating the problem, most amputees (up to 80%) suffer from sensation loss (neuropathy) in the stump making it difficult to maintain an appropriate ply within the prosthetic. Our device measures changes in socket pressure due to the daily and long-term limb volume change and adjusts to appropriate pressures accordingly. We also detect the activity state of the amputee and reduce

pressure while sitting. This allows the limb to recover fluid volume while sitting, which has been shown to be important for limb health. We anticipate improved quality of life outcomes due to better limb health.

Market Demographics

The US market is approximately ½ the total available. In the US alone, the total available market for our device is the 140,000 new annual lower limb (LL) amputations and the 1,400,000 living LL amputees where 80% of those have neuropathy. The number of existing LL amputees is predicted to double by 2050. Annual expenditures by Medicare alone account for \$700M for prosthetics today. (AOPA)

Value Proposition

The socket system we are preparing for user trials is intended to reduce skin breakdown and bruising injuries associated with lower limb prostheses by actively controlling applied pressure. This will reduce rework of the socket to relieve “hot” spots and reduce the need for new sockets as the limb volume changes beyond what could be managed by modification. Our value proposition is based in creating a longer use expectancy for the socket itself, fewer physician and prosthetist office calls due to injury, better patient health overall and a more satisfied patient. This combination is expected to save medical professional time as well as reduce medical treatment costs.

Furthermore, as a wirelessly-connected and sensor-enabled system, our device has the potential to add further value by providing user and medical practitioner data and simplified controls. Relevant data aspects may include overall mobility level, daily pressure and limb volume change tracking by user,

and more. Wireless connectivity will allow user adjustment of basic operation parameters, as well as a medical practitioner mode for setup, data analysis and advanced settings.

We are engineering a product for retrofit into all existing lock pin sockets (~90% of overall market), a second product that will fit all new sockets and a product that will work with all check sockets. This device should have a low regulatory hurdle as it will be a class 1 medical device under CFR 890.3420 External limb prosthetic component.

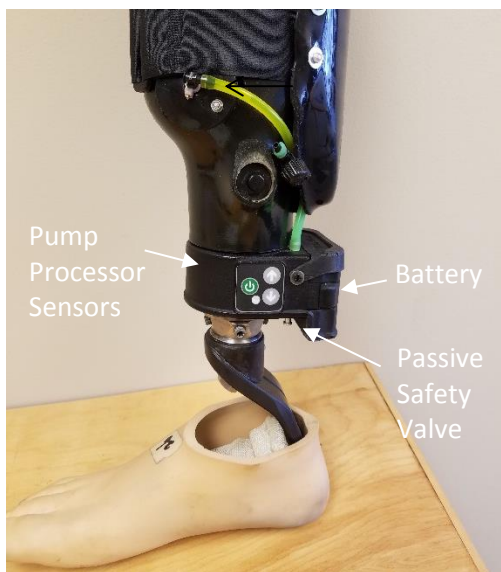
Milestones Achieved

- ✓ US & International patents filed
- ✓ LSDF research grant completed
- ✓ Prototypes built and running
- ✓ Initial test results attained
- ✓ Partnership MOU signed



Development Status

A 3rd generation of the device has been developed that is near production pedigree and intended for expanded initial user testing. Improvements focused on human factors, such as: safety, size, noise and battery life; as well as ease of prosthetist installation.



User testing is ongoing in two locations that is providing critical feedback towards a production level design. Revised requirements and design concepts are being developed for this final stage system.

An attractive business model exists with reimbursement under an existing code (L5646) with payback for added system cost being described in the Value Proposition section. A new code may be sought once user trials are able to demonstrate limb health improvement and overall medical expense reduction.

Business Strategy

It is the mission of Epoch Medical to develop mobility-enhancing intelligent control and actuation products that conform and adapt to the user.

Our business model is to focus on relevant industry problems that have market potential and seek OEM relationships who are looking for product suite enhancements. Our approach is to capture, develop and demonstrate relevant IP with highly functional working prototypes, then facilitate technology transfer to OEM partners.

The present system is nearing this final phase and we are considering all options to provide this beneficial system to the worldwide amputee community.

The Epoch Medical team is currently interested in evaluating new problems to be solved and expanding partnerships and networks with: OEM's, industry, academic institutions and government agencies.

Additional information and contact details are available at: www.epochmedical.com

Management Team

Michael Ballas - CEO, Founder
Research and Development Manager, Technical Sales/Business Development Manager with a 30-year career in aerospace.

Gary Ballas – CTO, Co-Founder
25-year career in design, development and engineering leadership. Former Director of Engineering & Quality for a \$100M+ aerospace firm.