iFIT PROSTHETICS®

We've created the Right Fit for today.

Immediate Fit | Innovative Technology | Adjustable Prostheses

"I was one week away from having above knee surgery due to the pain in my limb. Then, I was introduced to iFIT — the immediate comfort has given me my life back!"

- Diana

Overview

The principal business interest, a Wisconsin based company, iFIT Prosthetics LLC,® was founded in 2010 and is a Designated Veteran-Owned Small Business. Through nine years of NIH funding (STTR Phase I, II, IIB, and an SB1 Commercialization grant) adjustable transtibial (below knee) and transfemoral (above knee) prosthetic systems were designed, clinically tested, and commercialized with the goal of enhancing the lives of persons with limb loss and limb deficiencies. We are now very well poised to further advance care and expand our services. We are seeking like-minded companies, foundations, and international relief organizations to partner with us to enhance access to our high quality adjustable prosthetics. Through new alliances we want to make lower limb prosthetics readily available to persons who need them.

iFIT Prosthetics, LLC – was started to address the many shortcomings in conventionally fabricated prosthetic sockets. What continually struck Dr. Dillingham was the amount of time and effort invested into trying to make a hard socket fit a changing and compressible limb. His engineering background and familiarity with industrial manufacturing processes, along with his rehabilitation experience made him realize that prosthetic sockets could be adjustable, fit and aligned in a single clinic visit, and mass-produced using high strength injection molded polymer materials for high quality and consistency at more affordable prices.

Although mass produced and exceeding all industry strength and durability standards, our prosthetic system is customized to the individual amputee by means of a buckle system that adjusts to changes in their residual limb. We have an array of sizes to fit most persons. A soft neoprene liner inside the socket can be modified and additional padding placed at tender areas within the socket.

THE CURRENT STATE OF PROSTHETIC FABRICATION

Conventional manufacture of prosthetic devices is time consuming and labor intensive and results in a hard socket. Fabrication often requires three or more visits to the prosthetist with multiple steps in the fabrication process. First, a cast mold of the residual limb is made. Then a positive cast that resembles the residual limb is generated. The prosthetic socket is then built over the positive cast using laminated layers of materials and epoxy resins.

Contemporary 3D printing of digitized residual limbs at central fabrication centers has automated this process. However, these 3D sockets, like conventionally made hard sockets, are hard and non-adjustable and they do not account for tissue compressibility. iFIT sockets are priced at about one-fourth of the cost of conventional transtibial and transfemoral sockets.

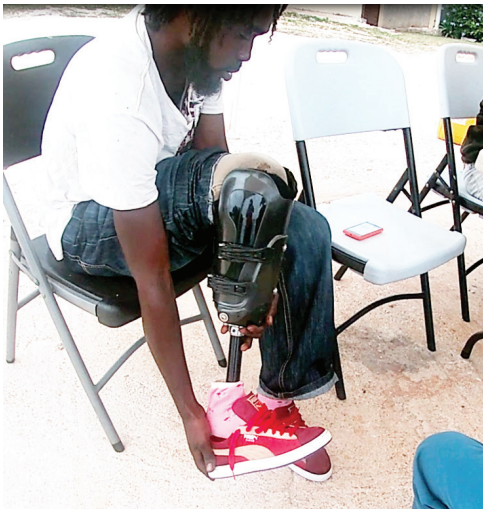
MARKETS FOR THIS PRODUCT

There is a great need for this device internationally. iFIT Prosthetics was started with the vision of a “prosthesis in a bag”. Our self-contained

> “The iFIT is noticeably cooler! Decreased stump perspiration in comparison to my traditional socket.”
>
> **- Frank**

prosthetic system is easily transported to impoverished nations or war torn countries and fit by healthcare professionals with some training regarding our device. We currently work with a physical therapist and prosthetist in Jamaica who fits patients with the iFIT device. The socket is very rugged and waterproof and has demonstrated that it holds up to very demanding use.

The United States market for this system is quite large and includes persons who experience volume changes in their residual limb shortly after amputation or because of heart and renal diseases. Children and adolescents with limb loss can benefit from the adjustability of the socket which accommodates growth.



A young man living in Jamaica with traumatic limb loss was unable to obtain a prosthetic for years until the iFIT device. He can farm again and his prosthesis (now worn for over a year) is durable enough to stand up to rugged terrain and demanding use.

This 13-year-old Jamaican boy has a congenital transtibial limb deficiency. Until he received the iFIT prosthesis, he had never walked other than with crutches. He was fit in a few hours and walked away from the clinic without crutches that day.

The iFIT Prosthetic System

ENGINEERING EXCELLENCE AND CLINICAL EXPERTISE

iFIT Prosthetics is fortunate to collaborate with an engineering firm in Wisconsin with considerable expertise—Advanced Design Concepts (ADC) Engineering, in Pewaukee, WI. ADC has worked with iFIT Prosthetics for over 8 years and brings a very important set of capabilities. ADC can design and prototype any concept regarding prosthetics. They are experts at injection molding and materials science. They also have the capacity to manufacture and ship finished prostheses efficiently and cost effectively.

These devices are clinically tested at the University of Pennsylvania in the Department of Physical Medicine and Rehabilitation (PM&R) biomechanics laboratory. These sockets are well received by persons with limb loss and in a prospective scientific study were found to be superior to conventional sockets in patient satisfaction and intrasocket pressures as documented in our most recent publication.

Summary of Innovation

iFIT Prosthetics successfully developed and commercialized an array of transtibial and transfemoral prosthetic sockets that are unique in the prosthetics industry. Over the past three years iFIT has commercialized these products to persons with limb loss and limb deficiencies all over the United States and internationally.

iFIT Prosthetics, LLC, is a company with the technical, engineering, and medical/prosthetic expertise (and patents that protect intellectual property) to change the way prosthetics are provided. The modular and mass produced nature of iFIT sockets provides value and access for patients and families to state-of-the-art adjustable prosthetics.

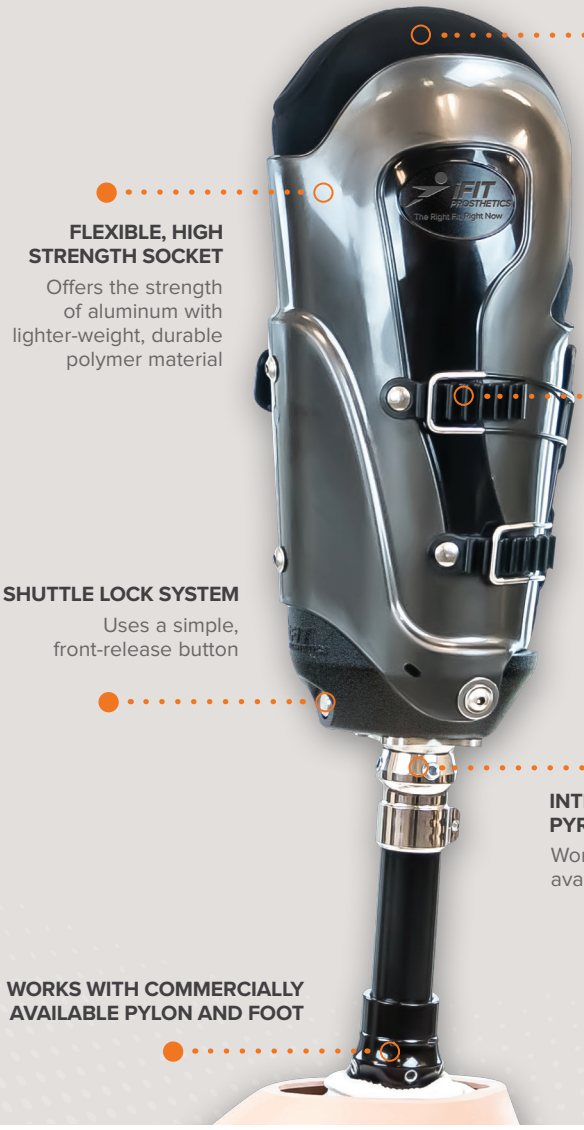
Our adjustable, immediate fit, prostheses represent the future of prosthetics — lower cost, higher value, modularity, and greater accessibility for patients in the United States and internationally.

The iFIT transtibial prosthesis is a modular, immediate fit, fully adjustable, transtibial prosthesis system made of high strength aerospace grade polymer materials – as strong as aluminum but lighter.

HOW IT WORKS

In contrast to conventional fabrication with casting, molding and shaping the socket that can takes weeks to complete, the iFIT prosthesis is fit and aligned directly on the residual limb in a single setting. The patient is immediately able to walk away with a comfortable and adjustable prosthesis. A buckle system with safety locks allows the patient to adjust the fit whenever they wish. The iFIT prosthetic system can be used with a variety of commercially available prosthetic feet and silicone locking liners. No other such product is currently available on the market.

TT200 PROSTHESIS



"I feel stable around my knee and I don't wobble as much as my other device. This is important because I'm a walker and always on the go."

- P.J.

Our Mission

Our mission is to produce high quality, affordable prosthetic devices that enhance the lives of persons with amputations.

Background

iFIT Prosthetics, LLC was founded by **Timothy R. Dillingham, MD MS**, a physiatrist who served in the US Army during the Persian Gulf War. Through eight years of continuous STTR funding from the National Institutes of Health (NCMRR, NICHD, and NIA), Dr. Dillingham and his team developed the first immediate fit, adjustable prosthetic sockets and brought these new devices from concept through to commercialization. During his many years of academic clinical practice, Dr. Dillingham was continually struck by the amount of time and effort invested into trying to make a hard socket fit a changing and compressible residual limb. This was the impetus for founding iFIT Prosthetics, LLC®.

His engineering background and familiarity with industrial manufacturing processes, biomechanics, and rehabilitation melded into creating a new concept for lower limb prosthetics. Dr. Dillingham realized that prosthetics could be manufactured more efficiently and with greater quality and consistency. The resulting iFIT adjustable sockets are far lower in cost and are more comfortable than conventional sockets – enhanced value for people with limb loss.

"According to a recent study submitted to NCOPE, author Dobson DaVanzo suggested that, by 2025, the number of prosthetic practitioners will drop by 60% to around 13,000, while demand will grow to over 20,000," Mullins states. "Such a gap affords Allard USA and iFIT the opportunity to step in with a great solution — an immediate fit prosthesis that requires no cast scans or molds, is fit and aligned in a single session, saves time and stress for patients with its full adjustability, reduces overall costs for prosthetists, and boosts quality and cost values across the board."

Scientific Validation

A Prospective Assessment of an Adjustable, Immediate Fit, Transtibial Prosthesis

We conducted an assessment of use, satisfaction, safety, and ambulatory function of the IFIT prosthetic device among a group of persons with transtibial limb loss using a prospective, observational, two-week follow-up study design. Key outcomes of interest were: i) patient-reported satisfaction with different aspects of the socket and device based on the Prosthetic Evaluation Questionnaire (PEQ); ii) objective measures of gait biomechanics, and iii) objective measures of intrasocket peak pressures. Twenty-two of the 26 subjects who agreed to participate in the study completed the protocol and contributed data for the analysis. No falls or limb ischemia were reported. There was a significant difference (p= .002) in self-reported overall satisfaction with the device in favor of the iFIT system (mean=30.9; SD ± 3.4) compared to the patients' own conventional device (mean= 24.8; SD ± 7.3).

Gait biomechanics revealed no differences in limp index, stride length, double support, stance phase, or walking speed between iFIT and the patient's own conventional device. Intra-socket peak pressures were significantly lower for the iFIT prostheses overall (p = .001), at the anterior tibia (p=.0002), and the lateral side of the residual limb (p=.013). With respect to strength and durability, there were no mechanical failures, despite high reported use (50% reported using the iFIT devices for 9+ hours per day during the 2-week trial).

All subjects successfully used the buckle closure system without any accidental opening or failure to fully lock in the closed position. Based on these results, the adult iFIT transtibial prosthetic system is a safe and well-received alternative to existing devices. The iFIT adjustable socket was superior to the subjects' conventional prostheses on self-reported satisfaction dimensions including comfort, and stability. Intrasocket pressures were significantly reduced in the padded iFIT sockets meaning less stress on the residual limbs. The biomechanical findings were all the same as for the conventional devices indicating that the iFIT device provided equal gait stability and patient confidence in walking as did the subjects' convention device. Results of this study were recently published by the PM&R Journal.

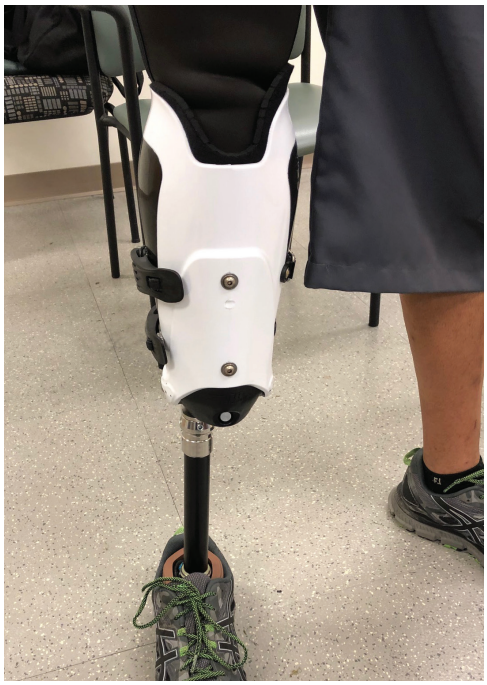
Timothy Dillingham, MD, MS, Jessica Kenia, MS, Frances Shofer, PhD, Jim Marschalek, MS. A Prospective Assessment of an Adjustable, Immediate Fit, Transtibial Prosthesis. Physical Medicine & Rehabilitation Journal. Published electronically.doi: 10.1002/pmrj.12133

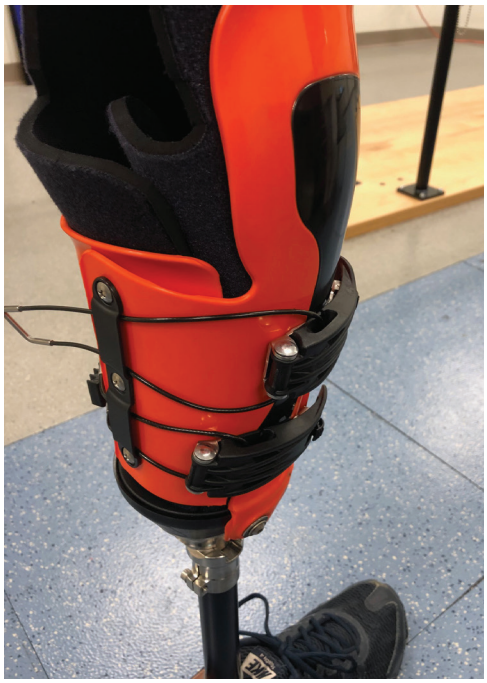
"The best part about my iFIT legs is that I don't have to worry about being in pain. **It's changed my life!"**

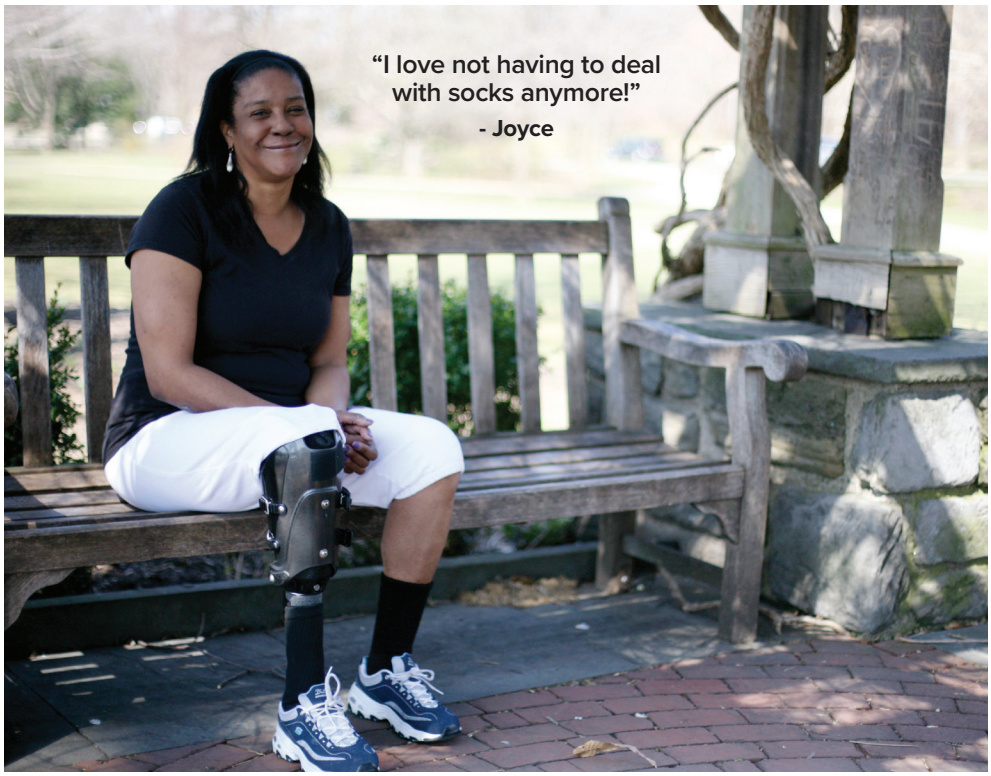
- Omar

Who is the iFIT for?

- Preparatory prosthesis for use during their first year after amputation when their limb is changing in shape and size.
- People who experience fluctuations in limb volume—particularly those persons with heart and renal diseases — find the adjustability a tremendous benefit as they do not need to carry socks and change them throughout the day.
- People who want to experience a comfortable socket really like the iFIT socket with its soft well padded liner.
- Those persons who enjoy the outdoors will find that the iFIT prosthesis will stand up to any activities including the water and eliminate the risks of damage to their conventional device.
- The iFIT prosthesis is military grade tough — waterproof, strong, and durable. Our closure system will not break even with demanding use.







"Instead of having to carry a special cover-up or silicone sleeve, I can simply hook on my durable iFIT water leg and go. It's quick, simple and great for my active lifestyle."

- Daniel

Life doesn't have to stop

With an iFIT device, you can get back on your feet quickly — with comfort and adjustability.

- Eliminates the need for sock changes during the day
- Mobilized earlier after amputation with a stable socket
- Tough, reliable and waterproof
- Fit and aligned in a single session

Adjust with iFIT!

Advantages

- Modular and mass produced with high level of quality controls that insure consistent strength and durability.
- Can be properly fit and aligned in 2 hours–the patient walks out of clinic with their prosthesis.
- Increases the efficiency of prosthetists
- Patient centered device that adjusts and accommodates volume fluctuations from daily edema changes in patients with heart or renal disorders.
- Accommodates longer term limb changes due to limb maturation after limb loss – it can serve as an ideal preparatory prosthesis.
- Reduces the tooling and manufacturing overhead costs for prosthetic facilities.
- This is ideal for International Relief Efforts in which no prosthetic facilities exist in a particular area. The iFIT prostheses can be shipped in bulk and fit with a minimum of tools in any setting - hospital, clinic, mobile medical centers (tents). A large number of persons can be fit successfully and in a very efficient manner with high quality, comfortable prostheses that will stand up to rugged and continuous use without breaking.
- Device exceeds International [ISO] Standards Testing for strength and durability.
- It works with many prosthetic feet and pin suspension liners.
- For large Health systems such as the Veterans Affairs Healthcare System, it can reduce overall prosthetic costs, while enhancing access to high quality state-of-the-art prosthetic care.

The iFIT prosthesis is a versatile product that we hope your patients will enjoy. For more information please visit our website at: www.ifitprosthetics.com or call Joshua Mullins, VP of Business Development at (301) 821-5414.

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