

# Capability Statement (December 20, 2024)

The mission of iFIT Prosthetics, LLC is to produce technologically advanced, high-quality, affordable prosthetic devices that enhance the lives of persons with lower limb amputations.

#### **Company Overview**

iFIT Prosthetics® is a Veteran-owned small business, established in collaboration with Advanced Design Concepts in Pewaukee, Wisconsin. For the past 15 years with Small Business Technology Transfer (STTR) grants from the NIH, Dr. Dillingham and his team developed and commercialized adjustable, immediate-fit, lower limb prosthetics for adults, children, and adolescents. iFIT pioneered subischial adjustable transfemoral sockets and adjustable supracondylar transtibial sockets.

His engineering background and familiarity with industrial manufacturing processes, made him realize that prosthetic sockets could be adjustable, fit and aligned in a single clinic visit, and mass-produced for high quality and consistency at more affordable prices. They can help address health disparities in the United States for persons with lower limb loss.

# CEO and Founder: Timothy Dillingham, MD, MS

Dr. Dillingham's entrepreneurial spirit led him to found *iFIT Prosthetics LLC* in 2010, to address the many shortcomings in conventionally fabricated lower limb prosthetics. His engineering background and familiarity with industrial manufacturing processes, made him realize that prosthetic sockets could be adjustable, fit and aligned in a single clinic visit, and mass-produced for high quality and consistency at more affordable prices. They can help address health disparities in the United States for persons with lower limb loss.

iFIT offers a line of adjustable, immediate-fit prostheses proven to best meet the needs of patients with limb loss.

- Modular prosthesis
- Fit in a single visit
- No more casting, molding, fitting
- An adjustable socket facilitates early rehabilitation
- Ideal for a preparatory device as well as a definitive prosthesis



# **Company Governance**

# Timothy Dillingham, MD, MS - CEO

Liliana E. Pezzin, PhD, JD – Chief Financial Officer Ingram A. Dillingham, BA – Account Manager

# **Key Business Partners and affiliates:**

Jessica Kenia, MS – Social Media and Website Management, Research Coordinator Machele Brass BA – *Brass Design* Marketing Jim Marschalek, MS – *Advanced Design Concepts* Lead Engineer. Sarah Spencer – *Advanced Design Concepts* Operations

#### **CORE CAPABILITIES**

- Production and distribution of up to **100 iFIT devices per month**.
- Lead Time for Domestic Orders: **One week**
- Lead Time for International Orders: Ships in 2 weeks
- Manufactured in Pewaukee, Wisconsin, a fully U.S.-made product.
- All our devices are waterproof.
- Injection molded prosthetic device using high-strength proprietary materials.

# **DIFFERENTIATORS**

- Modular and produced with the highest levels of quality control to ensure consistency in strength and durability.
- Can be properly fit and aligned in about 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.
- Easily transported in bulk to locations where they are needed such as international relief efforts for impoverished and war-torn countries.
- The iFIT device can then be fit easily and with minimal tools to a large number of persons with limb loss efficiently and with high quality and comfort.
- Device exceeds adapted International [ISO] Standards Testing.
- It works with most 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.



### **Pricing**

We strive to provide the highest quality of prosthetic devices at affordable prices.

Current US dollar prices as of 12/20/2024 (not including shipping and handling or customs fees):

Transtibial TT200 series sockets: USD \$1500

TTAC Transtibial socket (pediatric and adult): USD \$1500

Transfemoral TT300 series sockets: USD \$1900

#### Warranty

One year for any manufacturer defects. We will fully replace the sockets.

#### **Return Policy**

We do not accept returns other than for a manufacturer defect or to exchange sizing. In this case all shipping costs are born by the prosthetist exchanging the device.

#### **Payment**

Wire transfers preferred Credit cards accepted Bank checks accepted

# Logistics, Shipping & Handling

Domestic devices are shipped through DHL, FedEx, and UPS. International shipping is conditional on custom arrangements with the purchaser.

#### **NAICS Codes:**

339113 Prosthetic Appliances and Supplies Manufacturing

#### **Patents:**

US 8470050

US 8491667

US 884575

US 10398577

US 10,806,608

US 11,382,775

US 11,7663,43

#### **DUNS:**

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#### **Quality and Durability**

Our sockets underwent extensive modified ISO testing. The devices strength and durability have been amply demonstrated by our many years of U.S. domestic sales as well as by iFIT users in many other countries; Botswana, Zambia, South Africa, Caribbean Islands, Australia, Denmark, Ukraine, Lebanon, Turkey, and Jamaica.

### Food and Drug Administration

Registered and approved as type 1 devices

#### iFIT Prosthetics is a Veteran-Owned Small Business (VOSB)



# **CE Mark Approved** Adjustable devices

#### **Mailing Address:**

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