

# **FDA approves Indego exoskeleton for clinical and personal use**

March 11 2016, by David Salisbury

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A young man is wearing an Indego exoskeleton. Credit: Parker Hannifin

The U.S. Food and Drug Administration (FDA) has given clearance to market and sell the powered lower-limb exoskeleton created by a team of Vanderbilt engineers and commercialized by the Parker Hannifin Corporation for both clinical and personal use in the United States.

"I'm really glad," said H. Fort Flowers Professor of Mechanical Engineering Michael Goldfarb who developed the exoskeleton with a team of engineers and students in his Center for Intelligent Mechatronics. "It is particularly gratifying because it is the first thing that has come out of my lab that has become a product that people can purchase, which hopefully will make a significant improvement in their quality of life."

Indego, which allows people paralyzed below the waist to stand up and walk, is the result of an intensive, 10-year effort. The initial development was funded by a grant from the National Institute of Child Health and Human Development. In 2012 Parker, a global leader in motion and control technologies, purchased an exclusive license to market the design and has worked closely with Goldfarb's group to develop a commercial version of the medical device.

"Parker has done an excellent job in running their leg of the relay race, bringing the exoskeleton to market in just three years," said Goldfarb.



An Indego powered exoskeleton. Credit: Parker Hannifin

Until recently "wearable robots" like Indego were the stuff of science fiction. In the last 15 years, however, advances in robotics, microelectronics, battery and electric motor technologies have made it practical to develop them to aid people with stroke and spinal cord injuries. The device acts like an external skeleton. It straps in tightly around the torso. Rigid supports are strapped to the legs and extend from the hip to the knee and from the knee to the foot. The hip and knee joints are driven by computer-controlled electric motors powered by advanced batteries. Patients use the powered apparatus with walkers or forearm crutches to maintain their balance.

"You can think of our exoskeleton as a Segway with legs. If the person wearing it leans forward, he moves forward. If he leans back and holds that position for a few seconds, he sits down. When he is sitting down, if he leans forward and holds that position for a few seconds, then he stands up," Goldfarb said.

Indego is the second exoskeleton to receive FDA certification for U.S. use. The first was a device produced by Rewalk Robotics Ltd. However, Indego's clearance came after completion of the largest exoskeleton clinical trial conducted in the United States. According to the Parker news release, "Over the course of more than 1,200 individual sessions, study participants were able to use Indego to safely walk on a variety of indoor and outdoor surfaces and settings with no serious adverse events."

One of Goldfarb's design goals was to give users the maximum amount of personal freedom possible. One of his requirements, for example, was

to allow the user to put the exoskeleton on and take it off while sitting in a wheelchair. As a result, the Indego is considerably lighter and less bulky than the other exoskeletons under development.

Indego also has two features that are specifically designed to aid in rehabilitation:

- The amount of robotic assistance adjusts automatically for users who have some muscle control in their legs. This allows them to use their own muscles while walking. When a user is totally paralyzed, the device does all the work. The other designs provide full power all of the time.
- It is the only wearable robot that incorporates a proven rehabilitation technology called functional electrical stimulation. FES applies small electrical pulses to paralyzed muscles, causing them to contract and relax. FES can improve strength in the legs of people with incomplete paraplegia. For complete paraplegics, FES can improve circulation, change bone density and reduce muscle atrophy.

The innovative nature of the Indego design led Popular Mechanics to name Goldfarb one of its "Ten Innovators Who Changed The World" in 2013.

Beginning this summer, Goldfarb will head a four-year U.S. Department of Defense-funded study of the tangible economic and rehabilitation benefits of exoskeletons for people with [spinal cord injuries](#). This will be performed at three medical centers: James Haley Veteran's Hospital in Tampa (the first VA center in the country to use Indego), the Mayo Clinic in Rochester, Minnesota and the Vanderbilt University Medical Center.

People who use wheelchairs regularly can develop serious problems with

their urinary, respiratory, cardiovascular and digestive systems, as well as getting osteoporosis, pressure sores, blood clots and other afflictions associated with lack of mobility. The risk for developing these conditions can be reduced considerably by regularly standing, moving and exercising their lower limbs. The study, which will involve 24 participants, is designed to determine whether regular use of the Indego will also reduce these conditions.

Indego has been available in Europe since November, when it received the CE Mark, the European Union's equivalent of FDA approval. The initial price is \$80,000.

The next step is getting the device approved for health insurance reimbursement. This involves getting the Centers for Medicare and Medicaid Services (CMS) to approve a "rate code" for the exoskeleton: a numeric code that identifies the characteristics of patients who Medicare/Medicaid will reimburse for purchasing a given piece of medical equipment. Typically, the government will reimburse 80 percent of the cost of approved medical devices. In most cases private health insurance providers adopt the CMS code.

Provided by Vanderbilt University

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