A Major Step in the Right Direction

ActiGait® The Implantable Functional Electrical Stimulation System (FES) for Drop Foot

Information for end users from your clinician
I feel completely free.

Jochen was a board member of a multinational corporation, until a brain haemorrhage changed his life. Today, he has rediscovered inner peace and loves to go hiking.

Often it’s the minor obstacles in daily life that make it difficult to cope with an illness. As an example, many people who have suffered from a stroke can no longer lift their foot properly – this is called dorsiflexor weakness, or drop foot, and is caused by damage to the brain, one part of the central nervous system. Every step demands the utmost concentration, as well as being a frustrating reminder of the illness.

The implantable neurostimulator ActiGait® could therefore be an important step forward for those affected by drop foot or dorsiflexor weakness. It helps by activating the affected nerve with precise electrical pulses, enabling the foot to lift: one less obstacle on the way to independent living.

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Stroke
The primary cause of drop foot

According to the World Health Organization (WHO) over 15 million people suffer a stroke worldwide each year. Although more common an older age, an increasing number of young people are also affected, as the case of Kathrin shows on page 8. She suffered her stroke aged just 14.

Approximately one-third (5 million) of stroke sufferers are left with long-term disability. This can include walking difficulties such as those caused by drop foot. A common cause of drop foot is damage to the central nervous system, which is what occurs in stroke.

If the central nervous system is damaged, the brain can no longer correctly control certain parts of the body. As a result, the nerves in that area no longer receive the required signals in order to be able to activate the muscles in the coordinated pattern necessary for smooth walking.

Dorsiflexor weakness affects muscles in the lower leg and foot. The foot can no longer be lifted sufficiently or at all. Frequently during walking, rather than the heel of the foot being placed first, there is a tendency to scrape the toes along the ground, or set the entire sole down in one go. As a result, those affected have to concentrate hard on their walking at all times. Any crease in a rug, any uneven floor could become an obstacle. Stroke patients often swing the affected leg forward with their hip, walk on the outer edge of their foot, or grip with their toes. This requires great effort and can even lead to poor posture and backache.

Researchers looked for a way of artificially stimulating the nerves of the affected lower leg muscles. ActiGait® was developed to do just that. It can help those affected by sending electrical pulses that stimulate the nerves that activate the right muscles so that the foot can once again be lifted.
What happens during a stroke

During a stroke, as a result of either a brain haemorrhage or impaired blood flow, the brain cells are deprived of oxygen. Depending on the area affected and the duration of the stroke, neurological damage can occur. Often this is associated with paralysis on one side of the body.

Possible characteristics of dorsiflexor weakness after a stroke

1. Malposition of the foot, causing someone to walk on the outer edge of the foot.
2. Dorsiflexor weakness with forefoot strike. The heel no longer touches the ground when walking.
3. Malposition of the foot with clenched toes caused by spasticity in the affected foot.
The right pulse for your foot
This is how ActiGait® can help

It is well known that nerves and muscles can be activated by electrical impulses. ActiGait® harnesses this Functional Electrical Stimulation (FES) to make life easier for people with drop foot weakness caused by damage to the central nervous system following a stroke.

The surgeon places the implantable components of the ActiGait® system under the skin. This consists of a stimulator and a cuff electrode placed around the peroneal nerve. A small switch worn under the heel in a specially designed sock sends a signal when the foot is lifted. This signal triggers the control unit, which in turn activates the implant to deliver an electrical impulse to the cuff electrode and the nerve. The stimulated nerve activates those muscles in the lower leg responsible for lifting the foot, so that the affected foot can once again be lifted. This results in a balanced foot lift and a smoother and safer gait.

Without FES
To avoid stumbling, many drop foot sufferers swing the affected leg forwards from the hip in a half circle.

With ActiGait®
Should ActiGait® be suitable, the foot can be lifted again, and gait improves.
The evidence on the ground
What research says

One clinical study on stroke survivors with drop foot examined the impact of ActiGait®. The results showed that users were able to walk significantly faster after 15 months’ use of ActiGait®:

- The distance covered in 4 minutes increased by over 16 metres: an improvement of 13.83%.
- A defined distance of 20 metres was covered 20% faster with the use of ActiGait® compared to before the study, without ActiGait®.

Furthermore, the study demonstrated ActiGait® to be safe and showed that it was well accepted by users.

A survey among users showed that nearly 75 percent of the users stated that their quality of life had improved as a result of ActiGait®. Over 92 percent said that ActiGait® was very reliable and all were of the opinion that they preferred the implant over an orthosis.

FES may offer a variety of benefits:

- Lifting the foot at just the right moment
- Improving walking speed and pattern
- Making it possible to walk longer distances
- Walking requires less effort and concentration
- Improving spasticity
- Increasing mobility and activity
- Improving confidence and the feeling of security in everyday life

Sources:


Kathrin will never forget 29th January 2000. She was just 14 years old when she was overcome by a headache on the way to football training. Then she felt nauseous. This was followed by a tingling feeling on the left side of her body. Her coach called the emergency doctor. The diagnosis: stroke due to a tear in the carotid artery. Kathrin had three operations to remove the dead tissue of a large part of the right half of her brain. She was in a coma for almost three weeks.

After that, rehabilitation began for Kathrin. For a year she had to learn everything again – Kathrin made progress and experienced repeated successes. Some problems with walking remained as a result of the stroke, as she could not lift her left foot properly. Doctors at Göttingen University Hospital recommended ActiGait®. The neuroimplant considerably improved her ability to walk. Kathrin was mobile again and soon achieved her greatest wish – the 26-year-old was able to get a job. Today she works in a newspaper office.

"I was lucky that ActiGait® was suitable for me. I´m thankful that I can live more independently again."
ActiGait® is suitable for many stroke survivors, but there are also some exceptions, for example if the nerves in the leg are damaged or if the ankle cannot sufficiently be moved or stabilised.

For more information
Please visit our website:
www.dropfoot.co.uk

1 Initial examination:

You have been informed by your clinician about the treatment with ActiGait® and that it might be suitable for you. He or she should also provide information about contraindications and possible risks or side-effects.

A clinical specialist will test whether you react to electrical impulses and if you could benefit from ActiGait®, for example with the surface stimulator MyGait®. If you meet all requirements, you may qualify for an ActiGait® fitting.
2 Implantation:

3 Rehabilitation:

About three weeks after surgery and when the skin is healed, a clinical specialist activates and programmes ActiGait® according to your needs. The set-up will be fine-tuned further during two to three follow-up appointments.

ActiGait® is implanted in a procedure that takes approximately one to two hours. The stimulator as well as the cuff electrode will be implanted. The other components are worn externally on the body.
ActiGait® in Detail
How it works

ActiGait® is simple to use and easy to wear. The non-implanted components come conveniently packed in a handy carry case.

1 The control unit is lightweight and can be comfortably worn at the waist. Using a PC, the clinician programmes the control unit according to each individual user’s requirements. Users can also control the stimulation intensity to suit their changing daily needs. The control unit receives the signals from the heel switch and sends them directly to the antenna 2.

2 The antenna transmits these electromagnetic signals wirelessly through the skin and directly to the stimulator body of the implant. The antenna is held in place with an adhesive plaster, fixing it to the skin of the thigh.

3 The surgically implanted stimulator body converts the signals received into electrical impulses and powers the implanted cuff electrode.

4 The implanted cuff electrode has four stimulation channels and is placed around the peroneal nerve. When stimulated, this nerve activates those muscles of the lower leg necessary for foot lift. This stimulation can also control the eversion and inversion of the foot for a balanced lift.

5 The wireless heel switch registers when the foot leaves the ground and triggers the control unit to stimulate. The heel switch is worn in a specially designed sock so that the user can wear normal footwear and also walk without shoes. The heel switch controls the optimal timing for foot lift.

Please familiarise yourself with the special precautions in the product instructions.
Obviously, Jochen can never be happy about the brain haemorrhage that brought his life to a standstill in 2003. But he is grateful: grateful that he now appreciates the little things in life. Until then, this board member of an international corporation spent all his time in the fast lane. He’s still just as ambitious, but now he has other goals.

When Jochen came out of his coma, he could neither move nor communicate. He had to relearn how to live his whole life. He still has paralysis and drop foot on his right side. The man who used to run marathons could no longer even walk properly, not even, he says, "with orthoses and orthotic insoles".

In 2010, he had ActiGait® implanted at the Vienna’s general hospital. Since then, he rarely takes a step without it. Jochen has come to terms with his fate. "I’ve discovered a slower pace of life." He enjoys long walks with his dog and hiking with friends.

"Things are looking up again."
Safety information
ActiGait® is an active implant and medical device provided with the CE mark in compliance with the directives 90/385/EEC and 1999/5/EC.
You have been informed by your doctor about the treatment of ActiGait® for dorsiflexion weakness.
This brochure has been handed over to you by your doctor as part of medical care for general information. ActiGait® or FES is not suitable for all stroke patients with drop foot. Only a doctor can advise in detail about the treatment, contraindications and possible risks or side-effects.
Please familiarise yourself with the product information and read the instructions, which contain information about special precautions and possible adverse events.

Manufacturer
ActiGait® is a product of the Danish manufacturer Neurodan A/S. It is developed and produced with the greatest care and in conformity with the applicable European directives and national medical product laws. Unless otherwise expressly specified, warranty claims and other claims will be handled by the manufacturer.

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