The National Clinical FES Centre

Odstock Medical Limited
Salisbury District Hospital
Salisbury
Wiltshire
SP2 8BJ
U.K.

Telephone (01722) 429065
Fax (01722) 425623
enquires@salisburyfes.com

STIMuSTEP

IMPLANTED DROPPED FOOT STIMULATOR
PATIENT INFORMATION SHEET
November 2010 V1.2

Please take time to read the following information carefully and discuss it with others if you wish. Please ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to be considered for an implant.

Thank you for reading this.

Introduction

This document explains an implanted electrical stimulation treatment for people with a dropped foot as a result of damage to the brain and/or spinal cord. This includes people who have had a stroke (CVA), head injury, incomplete spinal cord injury or people with multiple sclerosis (MS), cerebral palsy or familial spastic paraparesis (FSP).

A new implantable nerve stimulator for the correction of dropped foot, known as the STIMuSTEP, has been developed by ourselves, Salford University (UK), the University of Twente and Roessingh Research. & Development in The Netherlands in collaboration with the UK based company, Finetech-Medical Ltd. The purpose of the device is to make walking easier, safer and faster for people who have a dropped foot as a result of damage to the brain and/or spinal cord. Dropped foot is dificulty in lifting the foot as the foot is brought forward, often causing it to drag or catch. By applying electrical pulses (Functional Electrical Stimulation, FES) to the appropriate leg muscles, the dropped foot can be corrected during walking.

Implantation of the device requires an operation, which will take about 1 hour and will be performed using a general anaesthetic in the Day Surgery Department. A single incision of approximately 7cm, on the outside of the lower leg just below the knee is required to site the device. In the unlikely event of something going wrong with the device or if you do not wish to continue using it, a second similar operation will be required to remove the implant.

How does the STIMuSTEP work?

The nerve that controls the lifting of the foot in walking is called the common peroneal nerve. At a point, just below the knee, this nerve splits into two nerve branches, the deep branch and the superficial branch. The deep branch goes to the muscles that lift (dorsiflex) and turn the foot inward (inversion) while the superficial branch supplies the muscles that turn the foot outwards (eversion). In normal walking, a combination of these movements is required. Therefore an electrode will be surgically inserted in both nerves, enabling the movements to be controlled separately. Figure 1 shows the electrodes, which are attached to the implanted receiver / stimulator using flexible silicon leads. To stimulate the nerve very short pulses of electricity are passed through each electrode, 30 times a second. This causes nerve impulses to travel down the nerve to the muscle in the same way as naturally occurring nerve impulses. Power to run the stimulator is passed through the skin using radio waves from a small control box strapped to the outside of the leg (figure 2). Figure 3 is a schematic diagram of system.

To stimulate the muscles at the correct time a foot switch (a small pressure pad placed in the shoe) is used to detect when the foot is lifted from the ground.

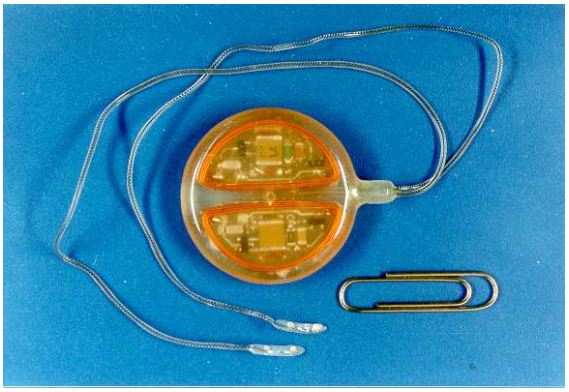

Figure 1. Implanted receiver stimulator

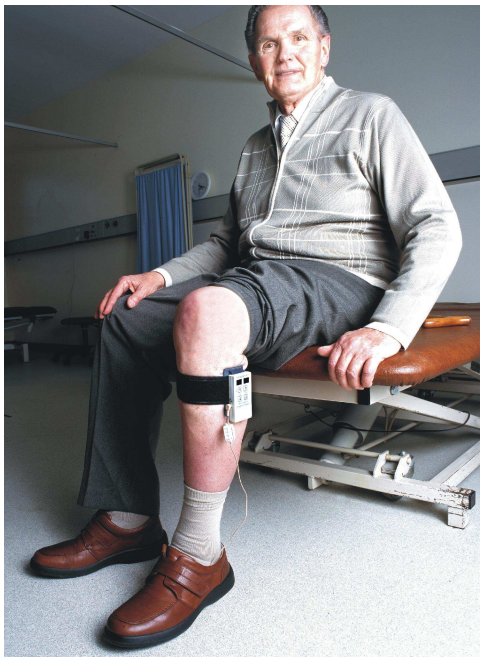

Figure 2. The implant controller

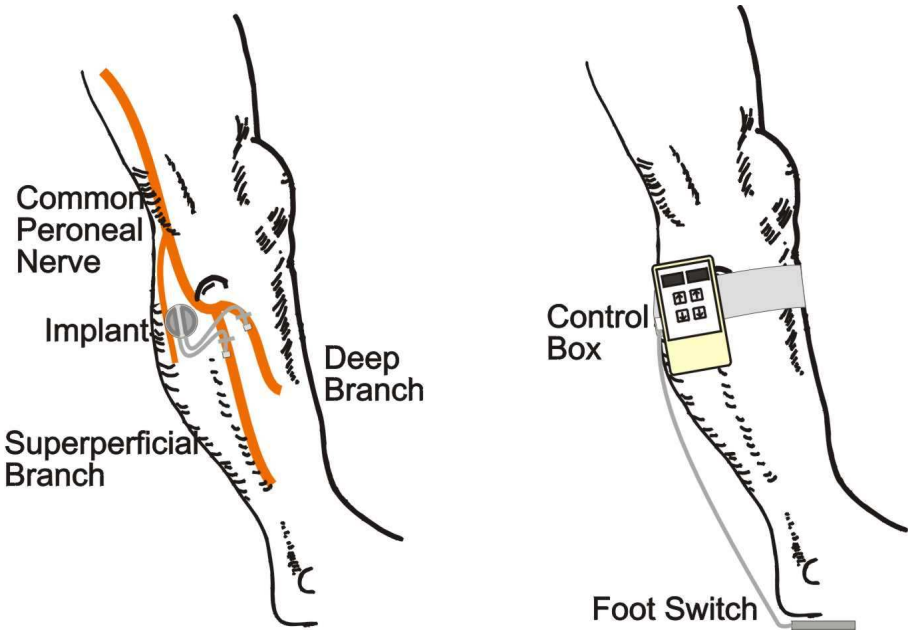

Figure 3 schematic diagram of the STIMuSTEP

Stimulation begins when the foot is lifted and ends when the heel is returned to the ground. Sensation from the electrical stimulation should be very slight and it is expected that users will quickly become accustomed to it. Use of the system will be automatic; the user only has to set the stimulation intensity using two control buttons. Once healing has occurred the operation site scar should be minimal. It may be possible to palpate the implant under the skin but it is not expected to be noticeable to the eye.

Am I suitable for the STIMuSTEP?

You might be suitable if you have had a stroke (CVA), head injury, incomplete spinal cord injury (T12 and above), multiple sclerosis (MS), cerebral palsy, familial/hereditary spastic paraparesis (F/HSP) or other neurological conditions effecting the brain or spinal cord. If you are not sure about your condition, discuss this with your GP or Consultant or call the telephone number at the end of this document. You will also fit the following selection criteria:

- Have a single dropped foot
- Be able to walk at least 50m with appropriate walking aid
- Be able to passively lift your foot so that the ankle joint is flexed upwards
- Have a stable medical condition or at least 1 year post injury
- Have no other significant medical complications such as diabetes, poorly controlled epilepsy or use a cardiac demand pacemaker
- Candidates must not have significant mental impairment as they must be able to understand the purpose of the treatment and be able to give informed consent.

The STIMuSTEP is NOT suitable for

- People with damage to the peripheral nervous system such as lumbar prolapsed discs, spinal injuries bellow T12, polio, nerve injury due to trauma to the leg
- People with a rapidly changing condition i.e. some people with MS
- People who are receiving immunosuppressive medication

Do I have to have an implant?
No, it is up to you to decide whether or not to receive the treatment. If you do decide to have the implant you will be asked to sign a consent form.

What will happen to me if I want an implant?
You will first be given an appointment for an assessment. At this appointment the treatment will be explained to you and your suitability assessed. You will not be pressed for an answer straight away but allowed time to make a decision. If you require further information you will be able to speak to members of the Department.

There are two ways to start the treatment. If you have already used an Odstock Dropped Foot Stimulator (ODFS) for more than six months then you can proceed straight to being assessed for the implant. If you have not used the ODFS or have used it for less than six months then you will be asked to use it for six months. In this way it is possible to see if your walking can be improved using surface FES without the need for an operation. This period of time can be used to decide if an implant operation is the best treatment for you.

The ODFS stimulates the same nerves as the STIMuSTEP but uses skin surface, self adhesive electrodes placed on the side of the leg below the knee. Electrical stimulation feels like pins and needles and most people quickly become used to the sensation. A small pressure pad will be put in your shoe, under the heel to control the device. (Figure 4)

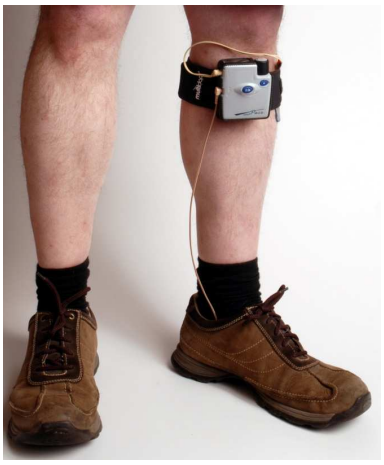

Figure 4. The ODFS

Treatment with ODFS involves an initial assessment to assess suitability for FES. You will then have an ODFS system set up for you over two consecutive days. On each day there will be an appointment of approximately one hour. Then we will see you again in six weeks and then three months later. At this appointment we will check if you wish to proceed with the implant. If this is the case, a new appointment will be made for you to discuss the operation with the surgeon and carry out additional assessments. If you decide that you do not want to have the implant you can cancel this appointment and still continue to use the ODFS.

The following assessments will be made during some of the above appointments:

- You will be asked to walk 10 metres to measure your walking speed and the effort you put into walking. You will be asked to do this both with and without the ODFS. Effort will be measured by recording your change in heart rate as you walk, using a small sensor strapped around the chest next to the skin.
- The spasticity (stiffness and involuntary activity) range of joint movement and muscle strength will be measured by a clinician.
- You will then be asked to walk for 3 minutes without stopping. The distance you walk will be recorded. If you tire before 3 minutes has ended then you can stop and the distance you have walked to that point recorded.
- Your walking will (with your permission) be videoed.
- You will be asked to complete several questionnaires about your walking and about your life.
- You will be asked to keep a 'falls diary'. In this diary you will record any occasions on which you trip and fall.

On the day of the surgery you will be asked to attend the Day Surgery Department in the morning. It is normal to be able to return home 2 to 3 hours after the surgery has taken place. You must be accompanied on your journey home and also for the first night after surgery. Also you will not be able to drive for 48 hours.

One week after the operation the wound dressing will be changed by your GP or district nurse. Three weeks after the operation you will return to the clinic to have the operative site checked and to start the use of the STIMuSTEP. At first only short distances will be walked with the device but this will be gradually increase over 2 or 3 weeks at which point it is expected that the device can be used all day.

You will be asked to return to the clinic usually 2, 8 and 18 weeks (4 months) later to check your progress and repeat some or all of the assessments. You will then attend the clinic 6 months after that and then yearly for as long as the device is used. If you experience any problems, staff will be available by phone or for extra appointments at all times.

So why use an implanted dropped foot stimulator?
It is expected that the STIMuSTEP will be easier to use than the ODFS because you will not have to find the correct position for the electrodes each time you put it on. Also, there will be less sensation from the stimulation and little risk of skin irritation.

The STIMuSTEP will be especially beneficial for

- People who have skin reactions when surface stimulation is used
- Younger patients likely to use the system for many years
- People who have experienced ongoing difficulty placing the surface electrodes used with ODFS
- People who are sensitive to the sensation of the surface stimulation

What are the alternatives for treatment?
The alternative treatments are to continue to use external FES or use a splints worn around to support the ankle.

What are the possible disadvantages and risks?
While everything has been and will be done to minimise problems, there are still some possible risks:

ODFS

- In some cases skin irritation can occur due to the self adhesive electrodes used. If this happens, then you are asked to contact us. We will provide advice on how to solve this problem.
- The stimulation feels like pins and needles. Most people quickly become used to it, but it is possible that you may find the sensation too uncomfortable and may decide not to use the stimulator. Similarly, turning the stimulation up too high may be uncomfortable, but not dangerous.

STIMuSTEP

- The procedure requires a general anaesthetic, which in rare cases can lead to medical complications.
- Infection as a consequence of surgery. If an infection becomes centred on the implant, it may be necessary to surgically remove the device. If you experience redness, pain, swelling and / or a raised temperature in the area of the implant you must contact your GP or the STIMuSTEP team as soon as possible.
- There is a small risk that nerve damage may result from the implantation of the electrodes. This may cause a reduction in voluntary movement and may mean that other electrical stimulation devices such as the Odstock Dropped Foot Stimulator or STIMuSTEP will not be able to be used. Nerve damage may also cause pain.

General

- Unexpected fall due to failure of the ODFS or STIMuSTEP

- In some cases people with spinal cord lesions above T6 can experience autonomic dysreflexia (rises in blood pressure, head aches or sweating) in response to electrical stimulation
- Some people who have epilepsy can have an increase in symptoms in response to electrical stimulation

What if I am not happy with an aspect of my treatment?
If you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of your treatment, please talk to a member of the clinical team or use the normal National Health Service complaints mechanisms.

Will my treatment be kept confidential?
All information collected about you during the course of this treatment will be kept strictly confidential. Each patient being implanted will be given a unique code that does not contain any personal details. Data will be collected but will be anonymised and confidentiality will be maintained at all times. The data will be used by members of the Department for audit purposes.

What will happen to the data taken at the assessments?
The results we obtain from the measurements at each appointment will be used to evaluate the effectiveness of the treatment and could help direct future clinical trials and FES treatment. Findings may also be published in scientific and medical journals, at conferences and at training days for clinicians. Confidentiality and patient anonymity will always be maintained. If you were interested, we would be pleased to discuss results and conclusions with you.

Contact for further information
If you need further information, please contact:
- Prof. Ian Swain; Head of department
- Dr. Paul Taylor; Clinical Engineer
- Ingrid Wilkinson; Physiotherapist
- Laura Humphreys, Physiotherapist

The National Clinical FES Centre
Odstock Medical Limited
Salisbury District Hospital,
Salisbury,
Wiltshire, SP2 8BJ.
Tel 01722 429065.

E-mail enquiries@odstockmedical.com
Web page www.odstockmedical.com

Referrals
Referrals by GP or Medical Consultant should be made to Prof. Ian Swain.

Thank you for reading this information sheet. If you wish to proceed, please either telephone or write to us at the above address.