















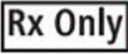

**eCoin® Peripheral Neurostimulator System
Patient Manual**



Valencia Technologies Corporation
28464 Westinghouse Place
Valencia, CA 91355 (USA)
www.valenciatechnologies.com
Tel: +1-661-775-1414

eCoin® is a trademark of Valencia Technologies Corporation, registered or pending registration in the U.S. and other countries.

Caution: U.S. Federal law restricts this device for sale by or on the order of a physician.

Label Symbols

Symbol	Description
	Manufacturer
	Catalog Number
	Serial Number
	Lot Number
	Refer to instructions for use (Consult accompanying documents)
	Temperature limitation
	Pressure limitation
	Do not reuse
	Sterilized using Ethylene oxide
	Do not re-sterilize
	Use by
	Do not use if package is damaged
	Caution: U.S. Federal law restricts this device for sale by or on the order of a physician
	Magnetic Resonance (MR) Conditional

	One (1) per package
	Fragile; Handle with care

Manual Contents

Who to Contact for Help?	7
Indications for use	8
Contraindications	9
What is eCoin Peripheral Neurostimulator Therapy?	10
Who it Helps?	10
The System.....	10
The Stimulation	12
Medical Procedure Precautions and Warnings	13
Effects on Other Implanted Devices	14
EMI Precautions	14
Precautions	15
Clinician training.....	15
Use in specific populations.....	15
Potential Adverse Events	16
Clinical Summary	18
Study Design.....	18
1. Clinical Inclusion and Exclusion Criteria.....	19
2. Clinical Endpoints.....	21
Clinical Study Patient Accounting	21
Study Population Demographics and Baseline Parameters	23
Safety and Effectiveness Results	23
Safety Results.....	23
All Adverse Events and Related Adverse Events	26
Patient Satisfaction.....	27
Getting the eCoin Peripheral Neurostimulator System.....	29
The Procedure	29
Tracking Your Symptoms.....	30

The Patient Controller	31
Patient Controller Safety Signs and Symbols	31
Patient Controller Warnings and Safety Notices	32
Patient Controller Instructions for Use	33
Storage Information	36
Contact Information	38
Living with the eCoin Peripheral Neurostimulator System	39
What to Expect	39
Support Resources	40
Follow-up Visits	41
Physical Activity Precautions	41
Medical Procedure Precautions and Warnings	42
Effects on Other Implanted Devices	44
EMI Precautions	45
At the Airport, Courthouses, etc.	46
Device Replacement	48
System Specifications	49

Who to Contact for Help?

Please contact your doctors if you have questions about your health or the eCoin therapy.

Valencia Patient Support

For questions regarding the eCoin Peripheral Neurostimulator System, additional information, and product manuals, visit our website:

www.eCoin.us/support

or call:

(833) ECOIN-US

For all warranty information, refer to:

www.eCoin.us/warranty

Indications for use

The eCoin Peripheral Neurostimulator is intended to be used to treat urgency urinary incontinence in patients intolerant to or having an inadequate response to other more conservative treatments or who have undergone a successful trial of percutaneous tibial nerve stimulation.

Contraindications

The eCoin Peripheral Neurostimulator is contraindicated for the following patients:

- **Poor Surgical Candidates:** The eCoin should not be implanted in patients who are poor surgical candidates. Poor surgical candidates include those who have:
 - Open wounds or sores on the lower leg or foot
 - Had prior surgery in the implant area
 - Had previous, unhealed trauma in the implant area
 - Pitting edema ($\geq 2+$) in the lower leg
 - Venous disease/insufficiency in the lower leg
 - Arterial disease/insufficiency in the lower leg
 - Vasculitis or dermatologic conditions in the lower leg
 - Infections near the implantation site in the lower leg
- Patient cannot properly operate the Patient Controller Magnets and paper tape for use in the event of unintended or unwanted stimulation.
- Patient does not have a history of sensitivity to neurostimulation

What is eCoin Peripheral Neurostimulator Therapy?

Who it Helps?

Millions of people suffer from urinary urge control symptoms. These symptoms can be frustrating, embarrassing, and uncomfortable. eCoin Peripheral Neurostimulator (“eCoin”) therapy may ease urge-related urinary control symptoms. This therapy is for people for whom other treatments did not work or who have undergone a successful trial of percutaneous tibial nerve stimulation.

eCoin therapy may help you if you primarily have these symptoms:

Urgency urinary incontinence – The unintentional loss of urine immediately after an urgent need to urinate.

eCoin therapy is not intended to help you if you primarily have these symptoms:

Stress urinary incontinence – Applied pressure on the bladder from physical movement or activity (such as coughing, laughing, sneezing, running, or heavy lifting) that causes urine leakage.

Patients with a history of sensitivity to neurostimulation may not be good candidates for eCoin.

The System

The eCoin Peripheral Neurostimulator System consists of 5 key parts:

- A small, nickel-sized, leadless implanted stimulator device (eCoin) that generates mild electrical pulses (**Figure 1**).

- A small, handheld External Controller device that allows trained technicians or your physician to program the eCoin (**Figure 2**).
- A small radio that allows trained technicians or your physician to monitor the programming of the eCoin.
- A small magnet that allows trained technicians or your physician to turn the eCoin off quickly during programming.
- A Patient Controller that allows you to stop or prevent eCoin stimulation in the unlikely event of stimulation discomfort.

The eCoin is implanted under the skin in your left or right leg near your ankle.



Figure 1a: eCoin Peripheral Neurostimulator

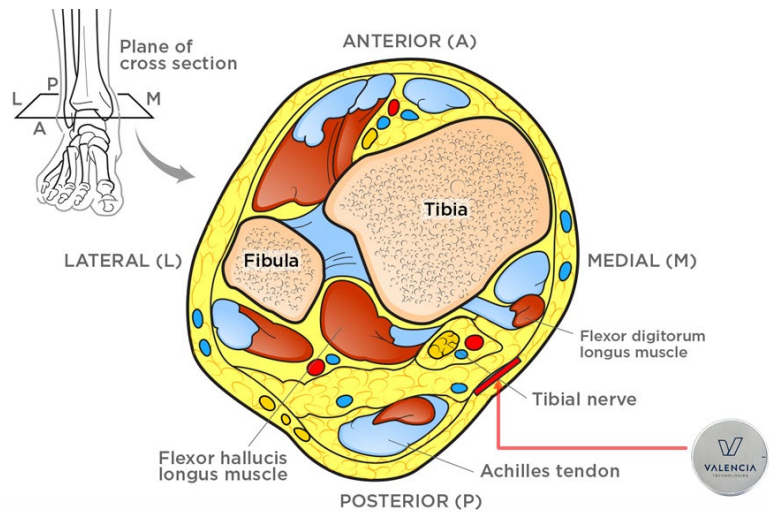


Figure 1b. eCoin placement in leg



Figure 2. External Controller

The Stimulation

The eCoin system delivers electrical pulses to the area of the tibial nerve located near the ankle in 30-minute sessions according to a fixed interval schedule.

The stimulation pulse intensity is adjusted to the level where you first feel stimulation. Trained technicians or your physician will adjust the intensity of the eCoin.

For the first 18 weeks of therapy, your 30-minute stimulation session will occur once every 3 days. After 18 weeks, your 30-minute stimulation session will occur once every 4 days. The time of day of stimulation may vary from session to session.

Some patients have described stimulation as a tingling or vibration sensation. The eCoin has a battery that should last for 1 to 8 years under expected and worst-case stimulation settings.

Medical Procedure Precautions and Warnings

Some medical procedures could damage your eCoin Peripheral Neurostimulator System. Those procedures, other implanted medical devices, as well as information regarding environmental electromagnetic interference (EMI) considerations can be found at the end of this document.

Talk to your doctor about your eCoin system before having any medical procedure.

Magnetic Resonance Imaging (MRI)

The eCoin Peripheral Neurostimulator is an MRI conditional device when kept 20 cm outside the bore of an MRI machine. It is not safe to have your lower leg placed in an MRI machine. Please refer to eCoin MR Labeling for more information.



MR Unsafe

The Patient Controller magnet is MR Unsafe and should never enter an MRI room or facility. The other parts of the eCoin Peripheral Neurostimulator System (used by your physician or a Technically Trained Field Person) are MR Conditional. Please discuss with your doctor how you can have an MRI, if necessary. You should present your eCoin registration card to MRI staff prior to having an MRI.

Effects on Other Implanted Devices

The effect of the eCoin system on the operation of other implanted devices, such as cardiac devices, other neurostimulators, and implantable drug pumps, is not known. In particular, if the eCoin device is implanted close to one of these devices, they may have sensing problems and/or may not function correctly. Potential interference issues should be investigated before surgery by clinicians involved with both devices. The programming of the devices may need to be optimized to provide maximum benefit from both devices.

EMI Precautions

Energy from equipment found at home, work, or in public can potentially interfere with the eCoin system. This is called electromagnetic interference (EMI). The eCoin system has features that protect from EMI. Most electrical devices will not affect the stimulator. Keep your distance from powerful electrical items to reduce the risk of potential problems.

If you think that an EMI generating equipment or environment is affecting the function of your eCoin system, you should:

1. Move away from the equipment or object.
2. Turn off the equipment or object (if possible).

If you are unable to eliminate the interference or believe the interference has altered the effectiveness of your therapy, you should contact your clinician.

Sources of strong EMI can result in the following:

- **Patient injury**, resulting from heating of the eCoin that causes damage to surrounding tissue.
- **System damage**, which may require surgical replacement due to change in symptom control.

- **Operational changes to the eCoin**, causing it to turn on or off or to reset the settings, resulting in loss of stimulation or return of symptoms, causing a need for reprogramming by the clinician.
- **Unexpected changes in stimulation**, leading to a sudden increase or change in stimulation, which may be experienced as a jolting or shocking sensation. While the sensation may be uncomfortable, the device would not be damaged nor would it cause direct injury to the patient. In rare cases, the change in stimulation may cause the patient to fall and be injured.

Precautions

Clinician training

Implanting clinicians should be trained on the implantation and use of the eCoin Peripheral Neurostimulator system.

Prescribing clinicians should be experienced in the diagnosis and treatment of urgency urinary incontinence and should be trained on the use of the eCoin Peripheral Neurostimulator system.

Use in specific populations

The safety and effectiveness of this therapy has not been established for:

- Pregnant women
- Patients under the age of 18
- Patients with progressive, systemic neurological diseases (e.g. Parkinson's disease, multiple sclerosis (MS), etc.)
- Bilateral stimulation – implantation of eCoin in both legs

Potential Adverse Events

Implantation and use of the eCoin Peripheral Neurostimulator System incurs risk beyond those normally associated with surgery, some of which may necessitate surgical intervention. In addition to the risks listed, there is a risk that eCoin therapy may not be successful in relieving symptoms or may cause a worsening of symptoms. These risks include, but are not limited to the following:

Risks associated with the eCoin placement procedure:

- Pain
- Infection
- Seroma (fluid build-up under the surface of the skin)
- Bleeding (bruising)
- Hematoma (collection of blood under the skin)
- Abscess (painful, swollen, infection-filled lump)
- Wound dehiscence (wound separation)
- Edema at the implant or incision site (swelling)
- Surgical injury to nearby nerves, vessels, or tendons
- Complications associated with the local anesthetic used during the procedure
- Blisters associated with the aftercare materials (ankle wrap)
- Patient use of anticoagulation (anti-blood clotting) therapies may increase the risk of procedure-related complications, such as hematomas or too much bleeding after the procedure.

Risks associated with the use of the eCoin system:

- Unwanted change in storage and/or voiding function (bowel or bladder)
- Device migration (movement)
- Device prominence (ability to feel the device through the skin)
- Device inversion (flipping) or extrusion (coming out through the skin)

- Allergic response or tissue reaction to the implanted system material
- Hematoma or seroma at the implant or incision site
- Skin erosion at the implant or incision site
- Persistent pain at the implant or incision site
- Tissue damage at the implant site
- Device toxicity effects and burns at the implant site
- Premature battery depletion
- Loss of therapeutic effect over time
- Uncomfortable or changed stimulation sensation
- Unintended or unwanted stimulation
- Reduced stimulation caused by a depleting battery
- Nerve injury
- Device failure
- Need for reoperation or revision

Clinical Summary

Valencia Technologies performed a clinical study to determine the safety and effectiveness of the eCoin System in the treatment of urgency urinary incontinence (UUI). The study was conducted in 15 US clinical sites and evaluated 133 patients. A summary of the clinical study is presented below.

Study Design

The study was a prospective, multicenter, single-arm trial to evaluate the safety and effectiveness of the eCoin System in subjects with urgency urinary incontinence (UUI). Across 15 sites, 133 subjects were enrolled. Procedures were performed primarily in office settings and all under local anesthetic. The study evaluated changes from baseline in UUI episodes as measured by voiding diaries and patient-reported outcomes through 48 weeks of eCoin therapy (which is equivalent to 52 weeks from device implantation). Patients who achieved at least a 50% improvement in the number of UUI episodes as measured in a 3-day voiding diary were considered therapeutic successes (“responders”). The key secondary effectiveness endpoint was the patients who achieved at least a 50% improvement in the number of UUI episodes per 24 hours on a 3-day voiding diary (“responder rate”) after 24 weeks of therapy.

The primary safety endpoint was to assess device-related, and surgical procedure-related adverse events from implantation (or attempted implantation) to 52 weeks after implantation of eCoin. The secondary safety endpoint was to assess the same at 28 weeks after implantation.

The eCoin neuromodulation device was implanted subcutaneously (underneath the skin) in the right or left leg of subjects with UUI. After a 4-week implant healing period, all subjects had a programming visit where the device was activated (turned ON). Once the device was activated, 30-minute stimulation sessions were delivered once every 3 days for the first 18 weeks, and once every 4 days thereafter. After 48

weeks (occurring about 52 weeks post-implant), the primary effectiveness and primary safety endpoints were assessed. A questionnaire of patient satisfaction and experience was also administered.

A Data Safety Monitoring Board (DSMB) monitored the study. A DSMB is an independent group of experts charged with reviewing study data for data quality and integrity, adherence to the clinical protocol, participant safety, study conduct and progress, and making determinations regarding study continuations, modifications, and suspensions/terminations.

1. Clinical Inclusion and Exclusion Criteria

Inclusion criteria

Women and men between the ages of 18 and 80 years of age with a diagnosis of overactive bladder (OAB) with urgency urinary incontinence or mixed urge and stress incontinence with a predominant urgency component (self-reported), for at least 6 months were enrolled in the study. In addition, to be enrolled an individual had to have at least one urgency urinary incontinence episode on each of three days as documented in a 3 day voiding diary. For the study, individuals had to be without pharmacological treatment of OAB (antimuscarinics and B3-adrenoceptor agonists) for 2 weeks prior to their baseline determinations or be intolerant of, or had an inadequate response to, any antimuscarinics, B3-adrenoceptor agonists or onabotulinumtoxinA. Subjects who had previous success with percutaneous tibial nerve stimulation were also enrolled.

Exclusion criteria

Subjects were excluded if they had predominantly stress urinary incontinence with more than 1/3rd stress urinary incontinent episodes when compared to total urinary incontinent episodes, and if they had urological or urogynecological structural abnormalities, e.g., bladder outlet obstruction, pelvic organ prolapse (POP). Other exclusion criteria

included prior surgical procedures for incontinence, subjects with interstitial cystitis, bladder pain syndrome and urinary tract infections (UTIs). Subjects with peripheral artery disease (PAD), chronic venous insufficiency (CVI), morbid obesity, uncontrolled diabetes, cancers of the urogenital tissues, and blood clotting disorders were also not enrolled. Individuals with neuropathies, or who have implanted stimulators or who have had treatment with sacral nerve stimulation or drug (onabotulinumtoxin A) were not enrolled.

2. Clinical Endpoints

There was a primary safety and a primary effectiveness endpoint as described below. “Responders” are defined as subjects achieving at least a 50% improvement in the number of UUI episodes per 24 hours on a 3-day voiding diary.

Safety – assessment of surgical procedure-related and device-related adverse events from implantation to 52 weeks after implantation of eCoin.

Effectiveness – to determine those patients who achieved a 50% or greater improvement in UUI episodes after 48 weeks of therapy.

Key Secondary Endpoints included:

Effectiveness – to determine those patients who achieved a 50% improvement in UUI episodes after 24 weeks of therapy.

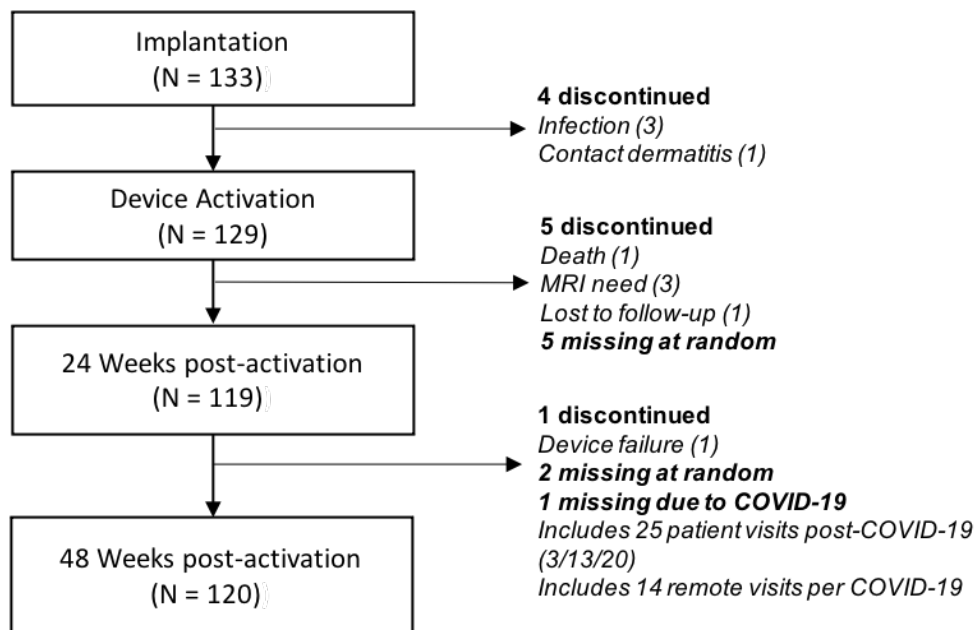
Other secondary objectives were based on data after 24 and 48 weeks from activation (28 and 52 weeks after implantation). The objective was to evaluate the effectiveness of eCoin with respect to the following outcome measures:

- Change in patient-reported overactive bladder condition utilizing the Patient Global Impression of Improvement (PGI-I) questionnaire
- Patient-reported satisfaction with eCoin therapy utilizing the custom patient satisfaction rating survey

Clinical Study Patient Accounting

After patient enrollment and clinical data was obtained, 137 patients had been enrolled in the clinical study. One (1) patient withdrew consent, one (1) patient exhibited significant non-compliance, two (2) patients

were not implanted given achievement of the recruitment goal. The remaining 133 patients were implanted, inclusive of zero (0) failed attempted implantations, with the eCoin. Of the 133 implanted patients, 119 and 120 attended the 24-week and 48-week visits, respectively, including remote 48-week visits. Additionally, eight subjects who were implanted were considered ineligible for the study. A flow-chart summarizing the patients treated can be found in **Figure 3** below.



Missing at random = Data for this participant is unavailable for listed visit below ONLY. No cumulative effect.

Figure 3: Clinical Study Patient Accounting (NOTE: Three of the subjects who were missing at random at 24-Weeks returned for their 36-Weeks visit. The remaining missing at random subject remained missing at random for the rest of the study.)

Study Population Demographics and Baseline Parameters

Subjects for this study ranged from 30 to 80 years of age, with an average age of 64 years. Ninety eight percent (98%) were female. Only one (1) subject was a current smoker. 84% of subjects were White, 5% were Black or African-American, 2% were American Indian or Alaskan Native, 2% were Asian, 1% were Native Hawaiian or other Pacific Islander, and 7% did not report their race. Additionally, 76% of subjects were not Hispanic or Latino, 17% were Hispanic or Latino, and 8% did not report their ethnicity.

Safety and Effectiveness Results

Safety Results

The analysis of safety was based on the 133 subjects implanted with the eCoin with follow-up through 52 weeks. On average, subjects had a permanent implant for 50.7 weeks.

The primary safety endpoint was to assess surgical procedure-related and device-related adverse events 52 weeks after implantation of the eCoin. The secondary safety endpoint was to assess device-related adverse events 28 weeks after implantation of the eCoin. Device- and procedure-related adverse events were reviewed.

Among the 133 implanted subjects, 52 weeks after implantation of the eCoin, a total of 23 subjects (17%) reported a device-related adverse event. Four (3%) subjects reported serious adverse events related to the device or procedure. No patient in the study reported having experienced severe stimulation pain. **Table 1** summarizes the adverse events up to 52 weeks post-implantation.

Table 1: Overall Summary of Adverse Events in All Implanted Subjects

Subjects with Adverse Events	Up to 52 Weeks Subjects (%)
Subjects with Any Adverse Events	79 (59)
Subjects with Serious adverse events	18 (14)
Related serious adverse events	4 (3)
Subjects with Non-serious adverse events	74 (56)
Procedure- or Device-related non-serious adverse event	25 (19)

Serious Adverse Events

Table 2 lists all serious adverse events (SAEs). There were four related serious adverse events—three infections and one contact dermatitis resulting in explant of the device. All other serious adverse events were unrelated to device or procedure.

Table 2: All Serious Adverse Events – All Implanted Subjects

Event Type	Total N=133 N (%)
Subjects with serious adverse events	18 (14)
Nervous	3 (2)
Encephalopathy (changed brain function or structure)	1 (1)
Hydrocephalus (fluid build-up in the brain)	1 (1)
TIA (“mini stroke”)	1 (1)
Cardiac	3 (2)
Atrial fibrillation (irregular heartbeat)	1 (1)
Left ventricular failure (heart failure)	1 (1)
MI (heart attack)	1 (1)
Infections	3 (2)
Implant site infection	2 (2)
Postoperative wound infection	1 (1)
Skin	1 (1)
Dermatitis contact	1 (1)
Surgical and medical	4 (3)
Hysterectomy	1 (1)
Knee arthroplasty	3 (2)
GI	1 (1)
Alcoholic pancreatitis	1 (1)
Hepatobiliary	1 (1)
Cholecystitis acute (gallbladder swelling)	1 (1)
Injuries	1 (1)
Fall	1 (1)
General	1 (1)
Chest Pain	1 (1)
Reproductive system	1 (1)

Female genital tract fistula	1 (1)
------------------------------	-------

Deaths

There was one (1) study subject death. The subject died as a result of an acute cardiovascular event unrelated to the device.

All Adverse Events and Related Adverse Events

Among the 133 subjects, a total of 27 subjects (20%) had device or procedure related adverse events (AEs). The most frequent were device stimulation issues occurring in 6 subjects (5%), and infection, occurring in 9 subjects (7%). Of the related events, 4 subjects (3%) were explanted and the event was resolved. The majority of related events were considered mild with three events determined to be severe. Among the 133 subjects, 79 subjects (59%) reported adverse events through 52 weeks.

Effectiveness Results

Study success was based on the proportion of patients treated who achieved at least a 50% reduction in their UUI symptoms at 48 weeks after implantation of eCoin. The results showed that 68% of the people treated with eCoin had a 50% or greater reduction in the number of urgency urinary incontinence episodes at 48 weeks, or were “responders,” in the intent-to-treat (ITT) population. In the per protocol population, 75% of the people treated with eCoin were responders. At 24 weeks, 69% of all subjects were responders in the ITT population.

Table 3 below summarizes the primary effectiveness endpoint.

Table 3: Primary Effectiveness

	<i>Proportion of Responders (%)</i>	<i>95% CI</i>
	<i>N = 133</i>	
Primary effectiveness endpoint		
48 weeks of stimulation		
Responder rate, with responder defined as subjects showing ≥50% reduction from baseline in the number of UUI episodes	68	60, 76

Patient Satisfaction

On the customer questionnaire rating satisfaction from completely satisfied to not at all satisfied, 61% and 63% of subjects reported being very or completely satisfied with the eCoin at 24 and 48 weeks, respectively. Subjects also reported their improvements in quality of life using a questionnaire called the Patient Global Impression of Improvement in Incontinence (PGI-I). On the PGI-I, 77% and 81% of subjects reported feeling at least better on the PGI-I at 24 and 48 weeks, respectively, with 34% and 39% of all subjects reporting the best

possible score of “very much better.” As an exploratory analysis, a final study questionnaire at 48 weeks also showed that only 3% of patients preferred any of the alternative treatments for overactive bladder (i.e., overactive bladder medications, percutaneous tibial nerve stimulation, botulinum toxin A bladder injections, and sacral neuromodulation) to eCoin.

Getting the eCoin Peripheral Neurostimulator System

The Procedure

The eCoin Peripheral Neurostimulator System will be implanted in a clinic procedure room or operating room. You will be given local anesthesia at the implant site. You will not be under general anesthesia for this procedure, meaning you will be awake for the duration of the procedure. You can discuss with your physician about any calming measures you might require for the procedure.

The eCoin will be implanted under the skin, above the tibial nerve near the ankle. Before the procedure, you and your doctor will decide which leg the eCoin will be implanted in. Since the eCoin is a leadless neurostimulator, only the eCoin is implanted.

Patients will go home on the same day as the procedure.

You may feel some pain or discomfort in the first couple of weeks after the procedure in the area of the implant as your skin heals. Your doctor may give you medication(s) to help with pain. Your doctor or their staff will give you detailed instructions on what to do following your surgery.

In the first few weeks after your procedure, you are advised to limit your activities, particularly activities that involve flexion (or pointing) of the foot, such as biking, dancing, or climbing stairs. Limiting activities will help avoid movement of your implanted eCoin to an unwanted position. When instructed by your doctor, you can go back to regular day-to-day activities.

Once you are instructed by your doctor, your eCoin will be activated and you will begin receiving stimulation. It is important to understand that the eCoin does not work immediately. If the eCoin works well for you, it

will take about 8 weeks for you to feel better and you may improve thereafter as well.

***Note:** Similar to any surgical procedure, there are risks with this procedure. Risks include bleeding, bruising, swelling, and infection. Please discuss the procedure and any concerns with your doctor.*

Tracking Your Symptoms

A diary is used to track your symptoms. You may need to fill out a diary for several days before your eCoin is implanted. The diary provides important information to your doctor that helps your doctor decide if you could benefit from eCoin therapy. It is important to fill out the diary when symptoms occur.

You should carry your diary with you when you are tracking your symptoms and use the diary to record symptom data.

Your doctor, or their staff, will show you how to complete your diary. You should contact them if you have questions.

The Patient Controller

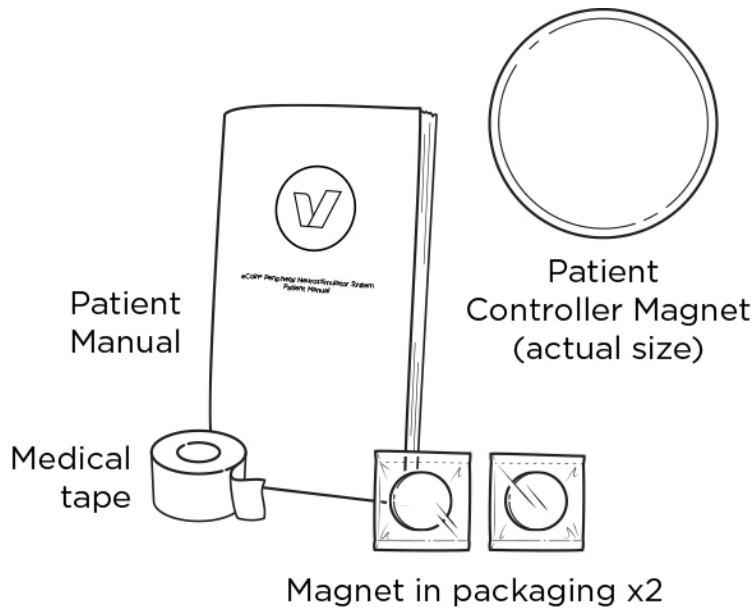










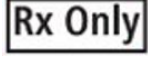


Figure 4: Patient Controller Kit contents

Your Patient Controller (**Figure 4**) is an important component of the eCoin system. In the event of severe discomfort or pain due to eCoin stimulation, the Patient Controller can be used to stop or prevent eCoin device stimulation. Please read through all of the information provided to properly use and maintain your Patient Controller.

Patient Controller Safety Signs and Symbols

Symbol	Description
	Manufacturer
	Batch Code

	Catalog Number
	Refer to instructions for use (Consult accompanying documents)
	Instruction to keep dry
	One (1) per package
	MR Unsafe
	Do not use if package is damaged
	Refer to instructions for use (Consult accompanying documents)
	Caution
	Caution: U.S. Federal law restricts this device for sale by or on the order of a physician

Patient Controller Warnings and Safety Notices

The Patient Controller is **NON-STERILE**, should **NOT** be applied to an open wound, and is indicated for **SINGLE-USE ONLY**. Contact with an open wound could cause an infection. Please do not modify the Patient Controller. Your Patient Controller is intended to be used only by you in the event of severe discomfort or pain from eCoin stimulation.

Do not wear or place the Patient Controller over implanted devices other than the eCoin. Other implanted devices such as pacemakers, defibrillators, and cochlear implants could be adversely affected.

The Patient Controller should not be exposed to an MRI environment.

The Patient Controller must be stored in the Patient Kit Box unless actively being used.

Patient Controller Instructions for Use

The Patient Controller is used to stop active eCoin stimulation. You will be provided two Patient Controllers as a safety precaution, to allow for an immediate stop of stimulation in the unlikely event of severe discomfort or pain from stimulation. The Patient Controller can be safely used to prevent future stimulation from the eCoin, if held or attached using the paper tape over the eCoin indefinitely.

The Patient Controller Kit (**Figure 4**) consists of the following components:

- Two **Patient Controllers (magnets)** are provided to stop eCoin stimulation. These magnets are in a silicone sleeve and a disposable plastic bag. The bag should be removed and discarded prior to use. Do not remove the silicone sleeve. When placed directly over the eCoin device, the magnet will stop active eCoin stimulation. If the magnet is placed over the eCoin device before stimulation is scheduled to start, it will prevent the next stimulation session from occurring. The Patient Controllers are NOT STERILE. They are intended for SINGLE USE ONLY. Only use one magnet at a time!
- **Paper tape** is provided to hold the magnet in place over the eCoin device.

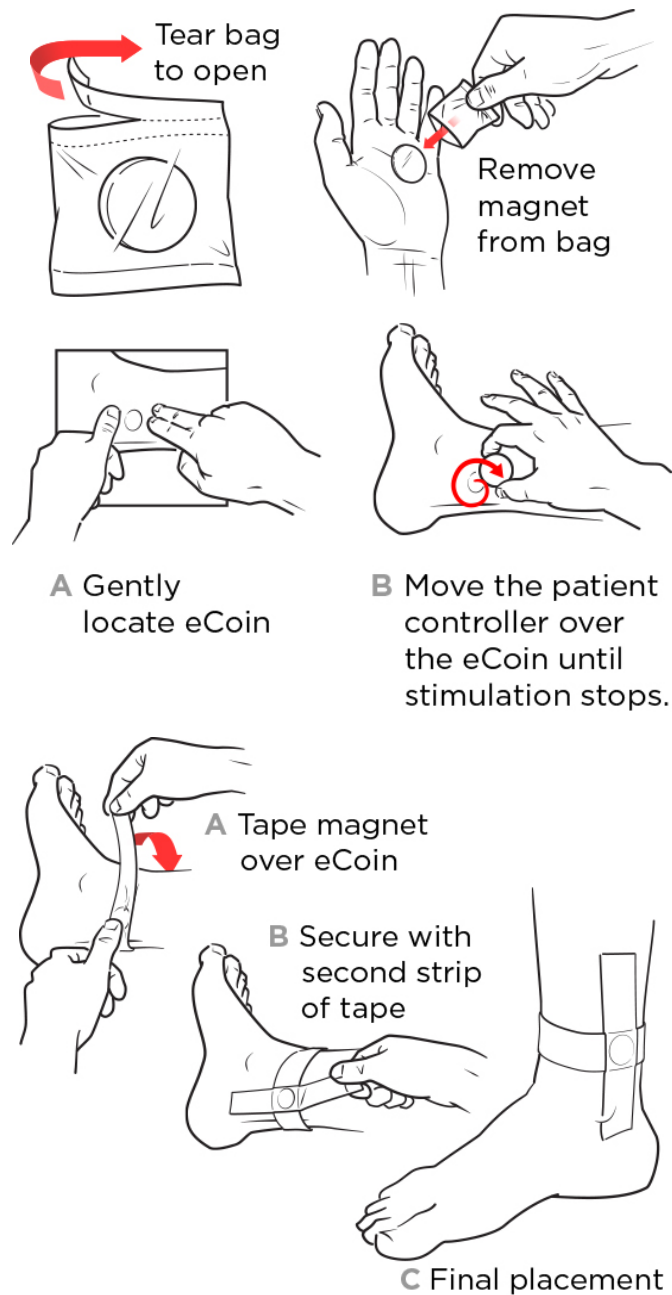


Figure 5: Patient Controller Instructions for Use

1. Tear open the Patient Controller bag along the perforation and remove the Patient Controller (magnet) from the bag.
2. Gently locate the eCoin.

3. Move the Patient Controller over the eCoin until stimulation stops
4. While holding the Patient Controller in place, wrap the paper tape around your ankle to secure the magnet.
- 5.



Dispose of the Patient Controller and all other used materials when you remove the Patient Controller from your ankle. Please dispose of the Patient Controller according to local law and regulation of rare earth magnets or return the Patient Controller to the company by mail in the Patient Kit Box.

Mailing address:

Valencia Technologies Corporation
28464 Westinghouse Place
Valencia, CA 91355 (USA)

*The magnet is NON-STERILE. Do not place the magnet directly on broken skin or an open wound.

Note:


1. If you use your Patient Controller, you should dispose of it. The second Patient Controller found in the Kit can be used in the event of a repeated need to stop stimulation.
2. Please notify your physician immediately should you have to use the Patient Controller. The physician will schedule an appointment to reprogram the eCoin device and order a replacement Patient Controller Kit.
3. In the event one of your Patient Controllers (magnets) breaks, please contact Valencia Technologies. Contact information is provided below.

Storage Information

Please store your Patient Controllers in a secure, but easily-accessible location to only you.

It is recommended that this location be in a dry and room-temperature environment.

Prop 65 Warning

 **WARNING:** This product can expose you to chemicals including ethylene oxide and lead, which is known to the State of California to cause cancer. The Aftercare kit can expose you to chemicals including naphthalene, ethylbenzene, and cumene which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

Contact Information

Please contact your physician, company representative, or Technically Trained Field Person for help with your Patient Controller.

You may also contact:

Valencia Technologies Corporation
28464 Westinghouse Place
Valencia, CA 91355 (USA)
www.eCoin.us/support
Tel: +1-833-ECOIN-US or 833-326-4687

Living with the eCoin Peripheral Neurostimulator System

What to Expect

Your eCoin will be turned on after your implant incision has fully healed and you have been approved for activation and return to regular activity by your doctor or a technically trained field person. You may feel tingling, pulsing, or vibration during active stimulation. It should not be uncomfortable or painful. Because eCoin delivers stimulation for 30 minutes once every three or four days, there will be large periods of time where you do not feel any stimulation. You may stop feeling stimulation over time. It is not important to the therapy that you feel each stimulation session.

If your therapy feels uncomfortable or painful, your doctor or a technically trained field person can change the stimulation. It may take more than one attempt by your doctor or technically trained field person to set the stimulation setting that is both comfortable and provides symptom relief.

In the unlikely event that the stimulation therapy feels extremely uncomfortable or painful, you can use the Patient Controller to immediately stop stimulation from the eCoin. When left over the eCoin device, the Patient Controller will prevent future eCoin stimulation as long as the Patient Controller is applied. Please contact your physician to notify of this severe pain or discomfort, and a follow-up visit will be scheduled to remedy the issue.

During the activation visit, once the stimulation setting has been programmed, the physician or technically trained field person will calculate your eCoin device's service life expectancy. You will be provided with the approximate date that your eCoin will be expected to stop functioning. Your physician will be notified 6 months prior to this

projected end of service life date, to provide ample time to schedule a device exchange or removal procedure, in accordance with your preference. The device exchange procedure will involve surgically removing the eCoin device with the expired battery and implanting a new eCoin device. The device removal procedure will involve only surgical removal of the eCoin device.

If the eCoin works well for you, it may take up to about 8 weeks to feel better.

The following items are important for managing your eCoin system:

- Follow-up appointments
- Your patient information card
- Your Patient Controller
- Precautions about physical activity
- Precautions about medical procedures
- Precautions about electromagnetic interference

***Note:** The feeling of your stimulation can change over time. Contact your doctor if your stimulation becomes uncomfortable or if your symptoms worsen.*

Support Resources

There are resources available to help you live with your eCoin Peripheral Neurostimulator System.

Training

You will be told about the precautions and warnings to be aware of. If you have questions or problems with your system, ask your doctor and his or her staff for more training or information.

Patient Information Card

You will be given a patient information card that contains basic information about you and your system. Your patient information card shows that you have an implanted stimulator if you have an emergency. Please keep this card with you when travelling outside your home. If you lose your patient information card, please contact Valencia Technologies for a new card.

Patient Controller

You will be provided with a Patient Controller Kit, which is comprised of several simple components. The **magnet** and **paper tape** are used to safely and effectively prevent eCoin stimulation in the unlikely event of severe discomfort/pain from stimulation, until a physician or technically trained field person is able to intervene. Please keep the patient controller with you when travelling outside your home.

Follow-up Visits

You will have regular doctor visits to check on your health and the eCoin Peripheral Neurostimulator System. Your doctor will help with problems and may change your stimulation settings. If you want to stop therapy, you should discuss this with your doctor. Your doctor may or may not advise removal of the eCoin system.

If the stimulation setting of your eCoin is reprogrammed during a follow-up visit, the physician or technically trained field person will recalculate your eCoin device's updated service life expectancy. You will be provided with the approximate date that your eCoin will be expected to stop functioning. Your physician will be notified 6 months prior to this projected end of service life date, to provide ample time to schedule a device exchange procedure.

Physical Activity Precautions

Patients should avoid activities that put the implanted system under extreme stress.

- Avoid rubbing the eCoin through the skin and activities that require excessive or repetitive stretching, or flexion, of the foot. These activities can damage the implanted eCoin resulting in loss of symptom relief and additional surgery. Examples of activities to avoid are gymnastics, mountain biking, sky diving, skiing, and other sports. Less extreme activities should not impact your system, like running, jogging, road biking, swimming, and sexual activity.
- Scuba diving below 8 meters (25 feet) of water or entering hyperbaric chambers above 150kPa should be avoided.
- Hiking or other high altitude activities at or above 10,000 feet above sea level (absolute atmospheric pressure below 70 kPa).
- A perceived increase in stimulation may be caused by electromagnetic interference, postural changes, and other activities. You may find this uncomfortable (a jolting or shocking feeling).
- You should change your posture (e.g., sitting, standing) during programming to confirm any changes in stimulation felt would not cause you to be unsafe during activities (e.g., driving).

Consult your doctor if you have any questions or concerns about physical activities.

Medical Procedure Precautions and Warnings

Some medical procedures could damage your eCoin Peripheral Neurostimulator System.

Talk to your doctor about your eCoin system before having any medical procedure.

Magnetic Resonance Imaging (MRI)

The eCoin Peripheral Neurostimulator is an MRI conditional device. It is not safe to have your lower leg placed in an MRI machine. Please refer to eCoin MR Labeling for more information.

The Patient Controller magnet is MR Unsafe and should never enter an MRI room or facility. The other parts of the eCoin Peripheral Neurostimulator System (used by your physician or a Technically Trained Field Person) are also MR Unsafe and should never enter an MRI room or facility.

Diathermy

Diathermy is a medical and surgical technique that involves the production of heat in a part of the body by high-frequency electric currents. Shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (collectively described as diathermy) should not be used on patients implanted with the eCoin system. Diathermy can transmit energy through the implanted system, potentially causing tissue damage at the location of the implanted electrodes, resulting in severe injury.

Other Medical Procedures

Additional medical procedures that may affect your eCoin system and should not be used in the implant area include:

- Monopolar electrosurgery (electrosurgery uses high-frequency electric currents to cut tissue or clot blood and in monopolar electrosurgery, the electric current is passed from a probe through your tissue to a return electric pad placed on your skin)
- Microwave ablation (an image-guided needle uses microwaves to create a small region of heat to destroy abnormal cells or tissues)
- Radiofrequency (RF) ablation (an image-guided needle uses high-frequency electrical currents to create a small region of heat to destroy abnormal cells or tissues)
- Radiation therapy over the eCoin
- Ultrasound or scanning equipment

Effects on Other Implanted Devices

The effect of the eCoin system on the operation of other implanted devices, such as cardiac devices, other neurostimulators, and implantable drug pumps, is not known. In particular, if the eCoin device is implanted close to one of these devices, they may have sensing problems and/or inappropriate device responses. Potential interference issues should be investigated before surgery by clinicians involved with both devices. The

programming of the devices may need to be optimized to provide maximum benefit from both devices.

Neurostimulator Interaction with Implanted Cardiac Devices

When a patient needs both an eCoin system and an implanted cardiac device (for examples, a pacemaker or defibrillator), interaction between the two devices should be discussed by the patient's physicians involved with both devices (such as the cardiologist, electrophysiologist, urologist, or urogynecologist) before surgery. **To reduce potential interference, the devices should be implanted on opposite sides of the body and as far away from each other as practical.**

The stimulation pulses produced by the eCoin system may interact with cardiac devices that sense cardiac activity, leading to inappropriate behavior of the cardiac device.

EMI Precautions

Energy from equipment found at home, work, or in public can potentially interfere with the eCoin system. This is called electromagnetic interference (EMI). The eCoin system has features that protect from EMI. Most electrical devices will not affect the stimulator. Keep your distance from powerful electrical items to reduce the risk of potential problems.

Everyday electrical devices are not likely to affect your eCoin. There are strong sources of EMI that have a higher risk. These include anti-theft detectors found in stores to detect stolen merchandise. If you encounter any such devices, walk far away from the sides of the device when passing through. Some anti-theft detectors may not be visible. If you feel unwanted stimulation or pain, walk away from that area.

At the Airport, Courthouses, etc.

Airport security systems should not cause any interference problems with your eCoin. Airport authorities advise patients to carry their Patient ID card with them when traveling. They advise you to walk through metal detector or security archways normally. Handheld security wands should move over the eCoin quickly. Fully-Body Scanners (millimeter wave scanners) are considered safe with implants by Transportation Security Administration (TSA). However, you should not linger within the detection zone.

You may encounter additional equipment that generates EMI. This equipment is unlikely to affect the eCoin system if you follow these guidelines:

Bone growth stimulators – The external coils of bone growth stimulators should be kept at least 45 cm (18 in) away from the eCoin system.

Dental drills and ultrasonic probes – The drill or probe should be kept 15 cm (6 in) away from the eCoin.

Electrolysis – The electrolysis wand should be kept at least 15 cm (6 in) away from the eCoin.

Electromagnetic field devices – The following equipment or environments should be avoided or you should exercise caution around:

- Antenna of citizens band (CB) radio or ham radio
- Electric arc welding equipment
- Electric induction heaters such as those used in industry to bend plastic
- Electric steel furnaces
- High-power amateur transmitters
- High-voltage areas (generally safe if outside the fenced area)
- Linear power amplifiers
- Magnetic degaussing equipment (equipment that disrupts and eliminates magnetic fields stored on tapes and disk media making the data stored on those devices unreadable)

- Magnets or other equipment that generates strong magnetic fields
- Microwave communication transmitters (generally safe if outside the fenced area)
- Perfusion systems
- Resistance welders
- Television and radio transmitting towers (generally safe if outside the fenced area)

Laser procedures – The laser should not be directed at the eCoin.

Psychotherapeutic procedures – Equipment used for psychotherapeutic procedures may induce electrical currents which may cause heating at the eCoin location and could result in tissue damage. Equipment that generates electromagnetic interference (e.g., electroconvulsive therapy, transcranial magnetic stimulation) during psychotherapeutic procedures have not been established as safe to operate in a patient with a neurostimulator. Induced electrical currents may cause heating, especially at the eCoin electrode site, resulting in tissue damage.

Radiation therapy – eCoin operation may be affected by high-radiation exposure. Sources of high-radiation should not be directed at the eCoin. eCoin damage due to high-radiation exposure may not be immediately evident, and exposure should be limited using appropriate measures, including shielding and adjusting the beam angle to avoid exposure to the eCoin.

Transcutaneous electrical nerve stimulation (TENS) – TENS electrodes should not be placed in locations where the TENS current passes over any component of the eCoin system. Discontinue using TENS if it starts affecting the performance of the eCoin system.

If you think that an EMI generating equipment or environment is affecting the function of your eCoin system, you should:

1. Move away from the equipment or object.
2. Turn off the equipment or object (if possible).

If you are unable to eliminate the interference or believe the interference has altered the effectiveness of your therapy, you should contact your clinician.

Sources of strong EMI can result in the following:

- **Patient injury**, resulting from heating of the eCoin that causes damage to surrounding tissue.
- **System damage**, which may require surgical replacement due to change in symptom control.
- **Operational changes to the eCoin**, causing it to turn on or off or to reset the settings, resulting in loss of stimulation or return of symptoms, causing a need for reprogramming by the clinician.
- **Unexpected changes in stimulation**, leading to a sudden increase or change in stimulation, which may be experienced as a jolting or shocking sensation. While the sensation may be uncomfortable, the device would not be damaged nor would it cause direct injury to the patient. In rare cases, the change in stimulation may cause the patient to fall and be injured.

Device Replacement

Information about the safety and effectiveness of device removal and replacement over an extended period of time is not known at this time. It is possible that the implant site could develop a scar tissue pocket that would not allow for a new device to be implanted after an old one is removed. Your physician should follow the most up-to-date recommendations about device replacement. When you reach the point of needing to have your device replaced, have a discussion with your physician about the most recent recommendations and the quality of your healed incision and device.

System Specifications

Battery life is estimated at nominal (average) and device maximum stimulation settings.

Nominal: 6 mA; Expected battery life: 3-5 years

Device maximum: 15 mA; Expected battery life: 1 year

You may choose to have your device replaced before the end of the battery life. Have a discussion with your physician if you choose to do so.

Table 3 shows the materials used in the eCoin package that touch human tissue.

Table 3: Human-Contact Materials

Implant Insulation	Silicone
Electrodes – Anode and Cathode	Platinum

Note: The eCoin case, which contains the electronics and power source, is hermetically sealed (sealed to be airtight).

Additional technical information is available. Please contact Valencia Technologies if you want to request additional information.

All Rights Reserved. Copyright 2020.
Valencia Technologies Corporation.