eCoin Peripheral Neurostimulator System

eCoin Physician Manual

Model UUI

Rx Only

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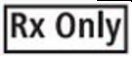
Label Symbols

This section explains the symbols found on the product and packaging.

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

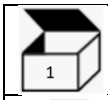
	One (1) per package
	Fragile; Handle with care
	Caution

Table of Contents

Introduction

This manual provides information about the eCoin Peripheral Neurostimulator, Model UUI for prescribing clinicians and implanting physicians.

Device Description

The eCoin (**Figure 1**) is part of the eCoin Peripheral Neurostimulator System. The eCoin is a programmable device which conducts stimulation pulses to the tibial nerve.

Figure 1: eCoin Peripheral Neurostimulator

Package Contents

The eCoin package contains the following:

- eCoin-UUI
- Two serial number labels
- Device registration form
- Patient implant card
- eCoin Physician Manual (this document)

The contents of the inner package are STERILE. The contents of the eCoin package are intended for single use only.

Patients will receive a kit containing Patient Controller Magnets and paper tape for use in the event of unintended or unwanted stimulation. The Patient Manual contains instructions for use for the Patient Controller Kit components.

eCoin Registration and Patient Implant Card

The device registration form registers the device and creates a record of the device in Valencia Technologies' implant data system. One of the device serial

number labels should be placed on the registration form, where indicated. NOTE: all information on the device registration form should also be recorded in the patient's permanent electronic record.

The patient implant card is removed from the registration form, filled out with the appropriate information, and provided to the eCoin patient. One of the device serial number labels should be placed on the back of the patient implant card, where indicated. The patient should carry the implant card at all times. Patients may also choose to obtain a medical ID bracelet or dog tag in addition to their patient implant card.

eCoin Peripheral Neurostimulator Therapy for Urgency Urinary Incontinence

Indications

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 (≥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 can not properly operate the Patient Controller Magnets and paper tape for use in the event of unintended or unwanted stimulation.

Warnings

Diathermy

Shortwave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (collectively described as diathermy) should not be used on patients implanted with the eCoin Peripheral Neurostimulator System. Diathermy can transmit energy through the implanted system, potentially causing tissue damage at the location of the implanted eCoin, potentially resulting in injury.

Magnetic Resonance Imaging (MRI)

The eCoin Peripheral Neurostimulator is an MRI Conditional system. It is not safe to have a patient's lower leg placed in an MRI machine. Refer to "eCoin MR Labeling" for more information.

The Patient Controller magnet is MR Unsafe and should never enter an MRI room or facility.

Non-clinical testing has demonstrated that the eCoin Peripheral Neurostimulator, Model UUI is MR Conditional. The patient having an eCoin-UUI implant can be safely scanned in an MR system meeting the following conditions:

- **Static magnetic field of 1.5 and 3.0 T**
- **Device remains at least 20 cm from the edge of the scanner bore**

<u>Heating by RF Fields – not tested</u>
When the patient is scanned with the device located outside the scanner bore, RF heating is not expected.

<u>Image Artifact – not tested</u>

Other Medical Procedures

Medical procedures that may affect the eCoin System and should not be used in the implant area include:

- Monopolar electrosurgery
- Microwave and Radiofrequency (RF) ablation
- Radiation therapy over the eCoin
- Ultrasound or scanning equipment

If electrosurgery must be used during other medical procedures, bipolar electrosurgery is favored and a 25 cm distance from the implant location should be kept. Monopolar electrosurgery should be avoided. If unavoidable, monopolar electrosurgery should be used in the lowest effective setting and the grounding pad should be placed as far away as possible from the eCoin and on the contralateral side.

If a patient must undergo a procedure during which an electrical current is passed through the patient's body, the eCoin System should be monitored. This can be done through patient feedback during the procedure (patient indicates discomfort or unexpected stimulation) and a device interrogation/programming procedure conducted by a Valencia Technologies representative after the procedure.

Electromagnetic Interference (EMI)

Electromagnetic interference is energy generated by equipment found at home, work, or in public that can interfere with the function of the eCoin Peripheral Neurostimulator System. The eCoin System includes features that provide protection from EMI so that most electrical devices encountered in a normal day are unlikely to affect the operation of the eCoin. While everyday electrical devices are unlikely to affect the eCoin, there are strong sources of EMI that may temporarily affect the operation of the eCoin, including anti-theft detectors found in retail stores. If patients encounter any of these electrical devices, they should walk as far away from the sides of the anti-theft detector when passing through.

At the Airport, Courthouses, etc.

If patients encounter walkthrough metal detectors or security archways, they should walk through at a normal pace. These detectors should not affect the eCoin. Hand-held security wands should be passed over the eCoin quickly and should not affect the eCoin. Full-body security scanners (millimeter wave scanners) are used by the Transportation Security Administration (TSA) and are considered safe in patients that have a stimulator. Patients should carry their patient identification card at all times and should have it available if TSA or other security personnel request it.

Additionally, patients should minimize their exposure by not lingering in the immediate area of the security systems. Some anti-theft detectors may not be visible. If patients feel unwanted stimulation or pain, they should walk away from the area and anti-theft detectors or security scanners. If the unwanted stimulation does not cease, patients should be instructed to use the Patient Controller magnet to inhibit device stimulation.

Case Damage

The eCoin contains battery chemicals that could cause burns if the eCoin case were ruptured or pierced.

Effects on Other Implanted Devices

The effect of the eCoin Peripheral Neurostimulator 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 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.

eCoin Interaction with Implanted Cardiac Devices

When a patient needs both an eCoin and an implanted cardiac device (for example, a pacemaker or defibrillator), interactions between the two devices should be discussed by the patients' physicians involved with both devices (such as the cardiologist, electrophysiologist, urologist, and 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 may interact with cardiac devices that sense cardiac activity, and disrupt the functioning of the cardiac device. The pivotal clinical trial of the eCoin device excluded patients with pacemakers and implantable cardiac defibrillators (ICDs).

Precautions

Clinician Training

Implanting Clinicians should be trained and certified by Valencia Technologies 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 (UUI) 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
- Bilateral stimulation

Clinician or Trained Field Person Programming

Full programming information and instructions can be found in the eCoin Technical Programming Manual and Tecsun PL-360 Technical Manual.

Amplitude Adjustment – The precaution below should be taken to prevent sudden stimulation changes that lead to an uncomfortable jolting or shocking feeling:

- The stimulation amplitude should be slowly increased to maximum. Please wait at least 5 seconds after triggering the eCoin device before adjusting amplitude to assure complete ramp up.

Sensitivity to Stimulation – Some patients may be able to sense the telemetry signals associated with reprogramming.

Programmer Interaction with a Cochlear Implant – Patients with cochlear implants should keep the external portion of their cochlear implant as far from the external controller as possible to minimize unintended audible clicks or other sounds.

Programmer Interaction with Flammable Atmospheres – The external controller is not intended to be used in the presence of a flammable gas, and the consequences of using the external controller in such an environment is not known.

Programmer Interaction with Other Implanted Devices – When a patient has an eCoin and another active implanted device (for example, a pacemaker, defibrillator, or other neurostimulator), the RF signal used to program any of these devices may reset or reprogram the other devices.

Whenever the settings for these devices are changed, a clinician familiar with each device should check the program settings of each device before the patient is released (or as soon as possible). Patients should contact their physician immediately if they experience symptoms that are likely to be related to the devices or their medical condition. For the eCoin, confirmation of the correct amplitude setting should be completed by adjusting the amplitude to the device minimum and then returning to the previously programmed amplitude.

Telemetry Signal Disruption from EMI – The eCoin should not be programmed near equipment that may generate electromagnetic interference (EMI) as the equipment may interfere with the external controller's ability to communicate with the eCoin. If EMI is suspected to be interrupting programming, the external controller and the eCoin should be moved away from the likely source of EMI.

Electromagnetic Interference (EMI)

Patients may encounter additional equipment that generates EMI. This equipment is unlikely to affect the eCoin if the patients 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.
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 patients 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
- 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 electrodes 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 the eCoin. Discontinue using TENS if it starts affecting the performance of the eCoin.

If a patient thinks that an EMI generating equipment or environment is affecting the function of their eCoin, the patient should:
1. Move away from the equipment or object.
2. Turn off the equipment or object (if possible).

If the patient is unable to eliminate the interference or believes the interference has altered the effectiveness of their therapy, the patient should contact their clinician or trained field person.

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
- **Operation 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 or trained field person.
- **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. If the patient experiences uncomfortable stimulation, they should be instructed to use the Patient Controller magnet to inhibit the stimulation output.

Patient Activities

Activities Requiring Excessive Twisting or Stretching – Patient activities that may strain the implanted eCoin should be avoided for 8 weeks after implantation. For example, movements that include sudden, excessive, or repetitive bending, twisting, bouncing, or stretching of the foot, ankle, or leg

may cause migration of the eCoin. eCoin migration may cause loss of stimulation or intermittent stimulation. Additional surgery may be required to replace or reposition the eCoin. Activities that typically involve these movements include gymnastics, mountain biking, and other vigorous sports. Clinicians should ask their patients about the activities in which they participate and inform them of the need for restricted activities during the first 8 weeks with the eCoin or until the clinician believes the implant and incision sites have healed enough to return to normal activities.

Component Manipulation by Patient (Twiddler's Syndrome) – Clinicians should advise patients to refrain from manipulating the eCoin through the skin. Manipulation may cause device damage, device migration, skin erosion, or uncomfortable stimulation.

Scuba Diving or Hyperbaric Chambers – Pressures below 8 meters (25 feet) of water (or above 150 kPa) could damage the eCoin. Diving below 8 meters (25 feet) of water or entering hyperbaric chambers above 150 kPa should be avoided. Patients should discuss the effects of high pressure with their physician before diving or using a hyperbaric chamber.

Skydiving, Skiing, or Hiking in the Mountains – High altitudes should not affect the eCoin as long as absolute atmospheric pressure remains above 70 kPa (approximately 10,000 feet above sea level). Patients should be cautious with strenuous activities due to the potential for movements that may put stress on the implanted eCoin. For example, a sudden slip or step while hiking may cause migration, which may require surgery to replace or remove the eCoin.

Unexpected Changes in Stimulation – A perceived increase in stimulation may be caused by electromagnetic interference, postural changes, and other activities. Some patients may find this uncomfortable (a jolting or shocking feeling). Before engaging in activities during which receiving a jolt would be unsafe for the patient or those around them, patients should discuss lowering the stimulation amplitude or turning the eCoin off with their clinician or trained field person. Patients should also be instructed on how to use the Patient Controller magnet in the event of unwanted or painful stimulation.

Storage Environments

eCoin Packaging – Any eCoin that has been compromised in any way should not be implanted. Do not implant the eCoin if any of the following have occurred:

- The storage package or sterile package has been damaged, pierced, or altered, as sterility cannot be guaranteed, which may lead to infection.
- The eCoin itself shows any signs of damage. The eCoin may not function properly.
- The use-by date has expired. In this case, eCoin sterility cannot be guaranteed and infection may occur.
- The sterile eCoin was dropped onto a non-sterile surface. In this case, the sterility cannot be guaranteed and infection may occur.

Shipping and Storage Environment:
The following lists the appropriate temperature conditions for shipping and storing the eCoin:

- Temperature (short term): -10°C to 55°C
- Temperature (long term): 10°C to 40°C
- Pressure: 70kPa to 150kPa
- Ambient humidity

If the eCoin is exposed to extreme temperatures, it may be permanently damaged and should not be used, even if it has returned to a temperature that is within the specified operating range.

Sterilization

The contents of this package have been sterilized using ethylene oxide gas. This device is for single use only and should not be re-sterilized.

eCoin Peripheral Neurostimulator System Implant

eCoin Failures – There is a possibility that the eCoin may fail. Failures such as electrical shorts, open circuits, and insulation breaches may occur. Also, the eCoin battery will eventually deplete. The eCoin should provide at least 1 year of service with a high degree of stimulation. Depending on amplitude settings, the battery will have a lifespan of 1-8 years. When the eCoin battery becomes depleted, the eCoin will need to be replaced.

eCoin Handling – The eCoin must be handled with extreme care. It may be damaged by excessive force or sharp instruments, which can lead to intermittent stimulation or loss of stimulation altogether and may require surgery to replace.

Potential Adverse Events Summary

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

<u>Risks associated with the eCoin placement procedure:</u>

- Pain
- Infection
- Seroma
- Hematoma
- Abscess
- Wound dehiscence
- Edema at the implant or incision site
- Iatrogenic 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 therapies may increase the risk of procedure-related complications, such as hematomas.

<u>Risks associated with the use of the eCoin system:</u>

- Adverse change in storage and/or voiding function (bowel or bladder)
- Device migration
- Device inversion or extrusion
- 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 stimulation

- Reduced stimulation caused by a depleting battery
- Nerve injury
- Device failure
- Need for reoperation or revision

Individualization of Treatment

The patient should be fully informed about the risks and benefits of implanted peripheral nerve stimulation therapy, including risks of the surgical procedure, follow-up responsibilities, and self-care requirements. In order to achieve optimal benefits from the therapy, the eCoin Peripheral Neurostimulator System requires a long-term commitment to post-surgical management.

Patient Selection – Patients should be carefully selected to ensure they meet the following criteria:

- The patient is an appropriate surgical candidate with special consideration for preexisting conditions in the lower leg, ankle, or feet that are incompatible with eCoin device placement. Some of the conditions that are incompatible with eCoin device placement include, but are not limited to:
    - Open wounds or sores on the lower leg or foot
    - Prior surgery in the implant area
    - Previous, unhealed trauma in the implant area
    - Pitting edema (≥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 can 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

Summary of Clinical Evaluation

Valencia Technologies performed a pivotal study to evaluate 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 UUI. Across 15 sites, 133 subjects were enrolled starting August 28, 2018, with the final implant occurring on April 12, 2019. 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, compared to baseline, were considered therapeutic successes ("responders"). The primary effectiveness endpoint was the proportion of patients that were responders after 48 weeks of therapy. The 3-day voiding diaries were self-reported and documented at least 3 days prior to the follow-up visit. The key secondary effectiveness endpoint was the proportion of patients achieving 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 adverse events from implantation (or attempted implantation) to 52 weeks after implantation of eCoin. The key secondary safety endpoint was to assess the same at 28 weeks after implantation.

The eCoin neuromodulation device was implanted subcutaneously 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.

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 β3-adrenoceptor agonists) for 2 weeks prior to their baseline determinations or be intolerant of, or had an inadequate response to, any antimuscarinics, β3-adrenoceptor agonists, or onabotulinumtoxinA. Subjects who had previous experience with percutaneous tibial nerve stimulation were also enrolled.

Exclusion Criteria

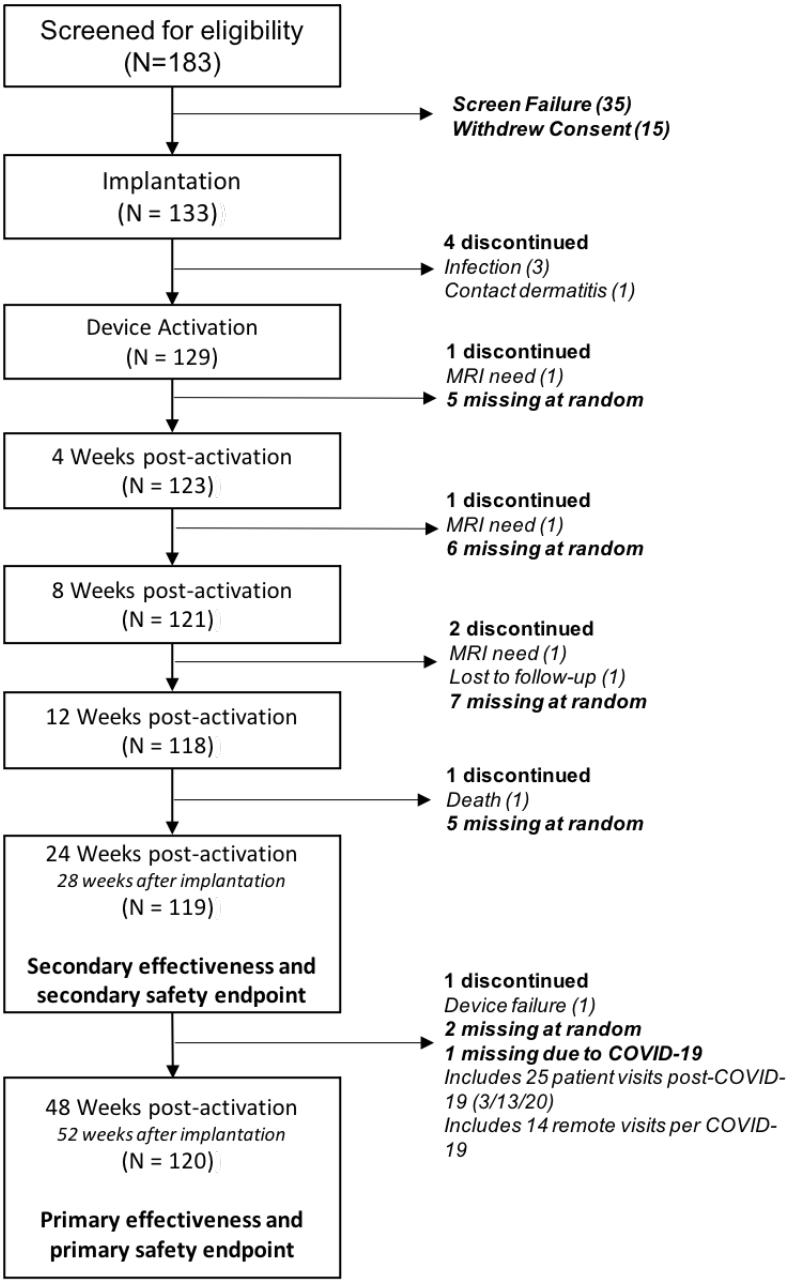
Subjects were excluded if they had predominantly stress urinary incontinence with more than 1/3rd stress urinary incontinent episodes when compared to total urinary incontinent episodes, and if they had urological or urogynecological structural abnormalities, e.g., bladder outlet obstruction, pelvic 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, who have implanted stimulators, or who have had treatment with sacral nerve stimulation or drug (onabotulinumtoxin A) were not enrolled.

2. Follow-Up Schedule

All patients were scheduled to return for an implant healing check 2 weeks after implantation, and an additional healing check and device activation 4 weeks after implantation. Once the device was activated, all patients were scheduled to return for follow-up examinations at 4, 8, 12, 24, 36, and 48 weeks. Adverse events and complications were recorded at all visits through 48 weeks post-activation of the eCoin device (52 weeks post-implantation). All analyses supporting this clinical investigation were complete at 52 weeks post-implantation. Subjects had the option of consenting to up to an additional 2 years of follow-up with annual study visits to collect longer term data.

Preoperatively, the patients completed a post-void residual (PVR) assessment and urinalysis. At each visit, the patients completed a baseline voiding diary, patient reported outcome questionnaires such as the Overactive Bladder Symptom Quality of Life Questionnaire (OABq) and Patient Global Impression of Improvement (PGI-I) questionnaire as well as a custom patient satisfaction survey.

A flow-chart summarizing the follow-up schedule, including the timepoints for each assessment and patient accountability at each timepoint, can be found in **Figure 2** below.



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

Figure 2: Flow-chart of Follow-up Schedule

3. Clinical Endpoints

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

Primary Effectiveness – assessment of the effectiveness of eCoin after 48 weeks of therapy. Effectiveness was defined as having a ≥50% reduction in UUI episodes per 24 hours on a 3-day voiding diary.

Key Secondary Endpoints included:

Safety – assessment of device-related adverse events experienced from implantation to 28 weeks after implantation of eCoin.

Effectiveness – to assess the effectiveness of eCoin on the proportion of responders after 24 weeks of therapy.

Other secondary objectives are based on data after 24 and 48 weeks from activation (28 and 52 weeks after implantation). These assessments were for descriptive purposes and were not hypothesis driven:

- Proportion of subjects achieving 75% improvement in the number of UUI episodes per 24 hours on a 3-day voiding diary
- Proportion of subjects achieving 100% improvement in the number of UUI episodes per 24 hours on a 3-day voiding diary
- 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

Accountability of the Pivotal Study Cohort

At the time of database lock, 137 patients had been enrolled in the clinical study. 1 patient withdrew consent, 1 patient exhibited significant non-compliance, 2 patients were not implanted given achievement of the recruitment goal. The remaining 133 patients were implanted, inclusive of zero failed attempted implantations, with the eCoin and were considered the intent-to-treat (ITT) population. Of the 133 implanted patients, 119, and 120 attended the 24-week and 48-week visits, respectively, including remote 48-week visits. A flow-chart

summarizing the ITT population can be found in **Figure 3** below. Eight subjects were implanted but later determined to be ineligible with regard to the inclusion exclusion criteria. These subjects remain in the ITT population but are excluded from the per protocol (PP) analysis population.

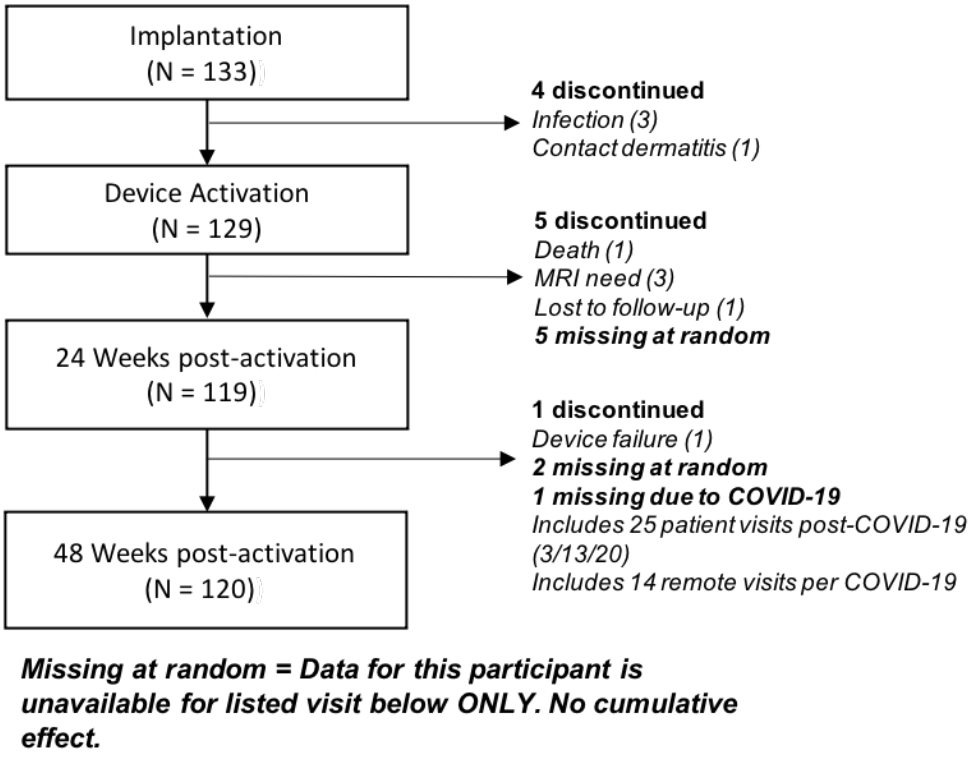


Figure 3: Accountability of Pivotal Study Cohort

Study Population Demographics and Baseline Parameters

The demographics of the study population can be found in **Table 1** below.

Table 1: Demographics – all implanted subjects

Demographics	**Total (n = 133)**
Age (years) at enrollment	
N	133
Mean (SD)	64.0 (11.0)
Range (min, max)	30, 80

Quartiles (25th, median, 75th)	59, 66, 72
Female, n/N (%)	131/133 (98)
Current smoker, n/N (%)	1/133 (1)
Race, n/N (%)	
White	112/133 (84)
Black or African American	6 (5)
American Indian or Alaska Native	3 (2)
Asian	2 (2)
Native Hawaiian or Other Pacific Islander	1 (1)
Not checked	9 (7)
Ethnicity	
Not Hispanic or Latino	101/133 (76)
Hispanic or Latino	22 (17)
Not known	10 (8)

Abbreviations: SD, standard deviation.

Safety and Effectiveness Results

Safety Results

The analysis of safety was based on the ITT population, which included 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 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 are provided as an exploratory analysis.

Among the 133 implanted subjects, 52 weeks after implantation of the eCoin, a total of 23 subjects (17%) reported a device-related adverse event. For each time window (28 and 52 weeks from device implantation), 20% of implanted patients reported at least one treatment-emergent AE related to the study device and/or

procedure. Four (3%) subjects reported serious adverse events related to the device or procedure. At 48 weeks, in an exploratory analysis, no patients reported severe stimulation pain. **Table 2** summarizes the adverse events up to 52 weeks post-implantation.

Table 2: 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 Any Procedure- or Device-related adverse events	27 (20)
Subjects with Serious adverse events	18 (14)
Procedure- or Device-related serious adverse events	4 (3)
Subjects with Non-serious adverse events	74 (56)
Procedure- or Device-related non-serious adverse events	25 (19)

Serious Adverse Events

Table 3 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 the device or procedure.

Table 3: All Serious Adverse Events – All Implanted Subjects

MedDRA System Organ Class/Preferred Term	**Total N=133 N (%)**
Subjects with serious adverse events	**18 (14)**
Nervous	**3 (2)**
Encephalopathy	1 (1)
Hydrocephalus	1 (1)
TIA	1 (1)
Cardiac	**3 (2)**

Atrial fibrillation	1 (1)
Left ventricular failure	1 (1)
MI	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	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 1 study subject death. The subject died as a result of an acute cardiovascular event unrelated to the device or procedure.

All Adverse Events and Related Adverse Events

Table 4 provides a summary of all related adverse events, both serious and non-serious, through 52 weeks. Among the 133 subjects, a total of 27 subjects (20%) had device or procedure related 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. During the study, eight subjects total were explanted: 4 due to related adverse

events (3 infection, 1 contact dermatitis), 3 for an MRI need, and 1 for device failure. One subject was revised for device dislocation. The majority of related events were mild in grade, with three graded severe. Severity was determined by the investigator and study site, not by the sponsor. Serious nature of an AE was determined by a clinically acceptable, pre-specified definition. Among the 133 subjects, 79 subjects (59%) reported adverse events through 52 weeks. Two subjects with related SAEs also had related non-serious AEs.

Table 4: Study-Related Adverse Events in the Intent-to-Treat Population

MedDRA Preferred Term	Non-Serious Study Related Subjects (%)	Serious Study Related Subjects (%)
Subjects with adverse events related to study device or procedure	**25 (19%)**	**4 (3%)**
Infections	**7 (5)**	**3 (2)**
Postoperative wound infection	5 (4)	1 (1)
Implant site infection	1 (1)	2 (2)
Wound abscess	1 (1)	0 (0)
Product Issues	**10 (8)**	**0 (0)**
Device stimulation issue	6 (5)	0 (0)
Device dislocation	2 (2)	0 (0)
Device malfunction	2 (2)	0 (0)
Injuries	**6 (5)**	**0 (0)**
Wound dehiscence	2 (2)	0 (0)
Incision site erythema	1 (1)	0 (0)
Incision site pain	1 (1)	0 (0)
Wound	1 (1)	0 (0)
Ligament sprain	1 (1)	0 (0)
General	**2 (2)**	**0 (0)**
Implant Site Swelling	1 (1)	0 (0)
Medical device site discomfort	1 (1)	0 (0)
Musculoskeletal	**2 (2)**	**0 (0)**
Musculoskeletal discomfort	1 (1)	0 (0)
Pain in extremity	1 (1)	0 (0)
Skin	**1 (1)**	**1 (1)**
Dermatitis contact	0 (0)	1 (1)
Skin irritation	1 (1)	0 (0)
GI	**1 (1)**	**0 (0)**
Anal incontinence	1 (1)	0 (0)

Effectiveness Results

The intent-to-treat (ITT) analysis of effectiveness is based on the 133 subjects at 24- and 48-weeks post-activation. The intent-to-treat population consists of all subjects who underwent a procedure for implantation of the eCoin device. The per protocol analysis of effectiveness is based on the 108 subjects at 48-weeks post-activation who did not have a major protocol deviation or take medications for overactive bladder during the course of the study. No imputation was done in the per protocol population.

All of the 133 subjects in whom an eCoin device was implanted or attempted to be implanted are included in the ITT population. All patients in whom an implant was attempted were implanted.

All subjects explanted, except those explanted for MRI, were treated as non-responders for any missing primary endpoint assessments. Subjects who had their device explanted for MRI had their missing data imputed. Any subjects for whom data was missing and the investigator did not know whether or not the device was in place were to be treated as non-responders. Subjects with missing data who are known by the investigator to have their device in place were assumed missing at random and handled with multiple imputation. All subjects undergoing a procedure, whether or not the device was activated, were to be treated as if the device was activated. One patient with a baseline UUI value of zero was treated as a non-responder.

The primary effectiveness endpoint was the ITT responder rate where responder is defined as a subject improving by at least 50% in their UUI episodes as compared to their own baseline at 48 weeks, post-implantation. The study primary effectiveness endpoint showing a 68% responder rate at 48 weeks (95% CI, 60, 76). At 24 weeks, 69% of all subjects were responders in the ITT population. In the per protocol population, 75% of subjects were responders. **Table 5** below summarizes the primary effectiveness endpoint.

Table 5: Primary Effectiveness: ITT population

	Proportion of Responders (SE) N = 133	*95% CI*
Primary effectiveness endpoint		
48 weeks of stimulation	**133**	
Responder rate, with responder defined as subjects showing ≥50% reduction from baseline in the number of UUI episodes	68 (4)	60, 76

Abbreviations: CI=Confidence Interval; SE=Standard Error; UUI=urgency urinary incontinence

The key secondary effectiveness endpoint was the responder rate at 24 weeks post-activation in the ITT population. At 24 weeks, 69% (95% CI, 61, 77) of subjects were responders. Additionally, 43% of subjects had 75% or greater reduction in their urgency urinary incontinence episodes at 48 weeks, and 21% of people showed 100% resolution of their UUI (dry).

The patient reported outcomes included the PGI-I, the OABq, and a custom satisfaction question. Patient outcomes are summarized in the ITT population. The OABq and PGI-I secondary endpoint results at 24 and 48 weeks are summarized below in **Tables 6 and 7**. Additionally, 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." On the custom satisfaction question 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. 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 urgency urinary incontinence (i.e., overactive bladder medications, percutaneous tibial nerve stimulation, botulinum toxin A bladder injections, and sacral neuromodulation) to eCoin. Exploratory analysis of the 48-week questionnaire demonstrated that 94/121 subjects (78%) planned to keep their device beyond 52 weeks, and 97% of patients reported that the procedure was explained to them adequately. Patients' attitudes toward the device were favorable compared to other therapies per the same questionnaire.
48-week questionnaire results are summarized below in **Table 8**.

Table 6: Patient Reported Outcomes: ITT population (all available data)

OABq Baseline and Change from Baseline at 24 and 48 Weeks	**N**	**Mean (SD)**	**Quartiles (25th, median, 75th)**	**Range (min, max)**
Baseline Symptom Bother	128	66.1 (19.6)	55, 65, 80	18, 100
24 Weeks Symptom Bother Change from Baseline (*decrease is better*)	116	-33.4 (26.8)	-55, -35, -14	-93, 23
48 Weeks Symptom Bother Change from Baseline (*decrease is better*)	116	-34.2 (27.5)	-55, -34, -14	-95, 33
Baseline HRQoL	128	45.7 (22.5)	29, 48, 62	0, 95
24 Weeks HRQoL Change from Baseline (*increase is better*)	116	+33.6 (27.6)	14, 32, 54	-25, 98
48 Weeks HRQoL Change from Baseline (*increase is better*)	116	+34.5 (25.9)	13, 33, 57	-15, 89

Table 7: Patient Reported Outcomes: ITT population (all available data)

Patient Global Impression of Improvement in Incontinence at 24 and 48 Weeks (*scale 1-7, lower is better*)	**N**	**Mean (SD)**	**Quartiles (25th, median, 75th)**
"Compared to how the subject's urinary leakage was before treatment, subject now reports that he or she feels" *1 – very much better* *2 – much better* *3 – better* *4 – about the same* *5 – worse* *6 – much worse* *7 – very much worse*			
24 Weeks	122	2.4 (1.3)	1, 2, 3
48 Weeks	120	2.3 (1.4)	1, 2, 3

Table 8: 48-Week Questionnaire Results (all available data)

	Total N = 132 n/N (%)	
Are you intending to keep the eCoin beyond today's 12-month visit?		
Yes	94/121	(78)
No	27	(22)
Would you prefer eCoin over overactive bladder medications (e.g., Myrbetriq, Detrol, Vesicare, Toviaz)?		
Yes	102/121	(84)
No	4	(3)
No preference	12	(10)
I am not familiar	3	(2)
Would you prefer eCoin over PTNS (Urgent PC/acupuncture)?		
Yes	97/121	(80)
No	3	(2)
No preference	6	(5)
I am not familiar	14	(12)
Not completed	1	(1)
Would you prefer eCoin over Botox for overactive bladder?		
Yes	90/121	(74)
No	5	(4)
No preference	6	(5)
I am not familiar	18	(15)
Not completed	2	(2)
Would you prefer eCoin over SNS (a pacemaker in the lower-back area)?		
Yes	99/121	(82)
No	4	(3)
No preference	1	(1)
I am not familiar	16	(13)
Not completed	1	(1)

Financial Disclosure

The Financial Disclosure by Clinical Investigators regulation (21 CFR 54) requires applicants who submit a marketing application to include certain information

concerning the compensation to, and financial interests and arrangement of, any clinical investigator conducting clinical studies covered by the regulation. The pivotal clinical study included 15 investigators of which six had disclosable financial interests/arrangements as defined in 21 CFR 54.2(a), (b), (c) and (f) and described below:

- Compensation to the investigator for conducting the study where the value could be influenced by the outcome of the study: none;
- Significant payment of other sorts: one;
- Proprietary interest in the product tested held by the investigator: none;
- Significant equity interest held by investigator in sponsor of covered study: six.

Conclusions

Effectiveness Conclusions

Effectiveness of the eCoin System was based upon the 133-subject prospective, multi-center pivotal trial in the United States.

The eCoin System demonstrated clinically meaningful improvements in incontinence, marked by a 68% (95% CI, 60, 76) responder rate at the primary endpoint of 48 weeks. Patients with a mean baseline UUI of 4.32 (SD 3.08) improved by a mean reduction of 2.61 (SD 2.97). Clinically meaningful improvements in incontinence were also seen at the secondary endpoint of 24 weeks, with a 69% (95% CI, 61, 77) responder rate.

Safety Conclusions

Through 52 weeks of follow up, 20% of patients reported device- or procedure-related adverse events. Most events were mild and four related adverse events were serious (resolved by explantation without sequelae). The procedure, performed under local anesthetic, was well-tolerated by patients.

Benefit-Risk Determination

The probable benefits of the eCoin System are based on the pivotal clinical study. Effectiveness was demonstrated by improvements in UUI as measured by voiding diaries. About 70% of patients, at all timepoints, achieved a 50% or greater reduction in daily UUI from baseline.

The adverse events reported were consistent with legally marketed neuromodulation systems. Through 52 weeks of follow up, 20% of patients reported device or procedure-related adverse events, four of which were serious (resolved by explantation without sequelae). The vast majority of procedures were performed in the office setting and most events were mild in grade.

In conclusion, the data described above support the use of the eCoin System for treatment of urgency urinary incontinence as the probable benefits outweigh the probable risks.

Patient Counseling Information

Clinicians should provide the following:

- Information about the eCoin Peripheral Neurostimulator System
- The Patient Controller Kit

Also, the clinician should provide each patient with a copy of the eCoin Peripheral Neurostimulator System Patient Manual and, in particular, review the following sections with them:

- Getting the eCoin Peripheral Neurostimulator System
- The Patient Controller
- Living with the eCoin Peripheral Neurostimulator System

Clinicians should also instruct their patients as follows:

- Patients should tell their healthcare professionals, including their primary doctor and dentist, that they have an implanted neurostimulation system. Patient should bring their eCoin Patient Manual to all medical and dental appointments in the event that their healthcare professional has any questions regarding the precautions to take and avoid potential device problems. Product manuals can also be accessed at www.eCoin.us
- Patients should contact their physician if they have any unusual signs or symptoms during healing, such as redness, tenderness, swelling, or fever.
- Patients should carry their Patient Controller with them at all times in case they need to stop stimulation from the eCoin in the event of severe

discomfort or pain. In this case, patients should also contact their physician.

- Patients should contact Valencia Technologies if their Patient Controller magnet breaks.

eCoin Disposal

The following steps should be taken when the eCoin Peripheral Neurostimulator System is explanted (for example, due to replacement, cessation of therapy, or after patient death) or when disposing of accessories:

- If possible, the explanted eCoin should be returned to Valencia Technologies along with completed paperwork for analysis and disposal.
- The device should not be autoclaved or exposed to ultrasonic cleaners to allow it to be analyzed by Valencia Technologies.
- Any eCoins not returned to Valencia Technologies should be disposed of according to local regulations. Please note that lithium batteries are hazardous materials and are subject to the U.S. Department of Transportation's Hazardous Materials Regulations (HMR; 49 CRF Parts 171-180).
- Any potentially contaminated materials should be treated as biohazardous waste.

Cautions:

- eCoins that are explanted or that have come into contact with bodily fluids should be handled with appropriate biohazard controls. Such eCoins should only be returned to Valencia Technologies in the appropriate biohazard packaging.
- The eCoin battery may explode if subjected to high temperatures; therefore, the eCoin should not be incinerated and should be explanted before patient cremation.
- Implantable devices should not be reused after exposure to body tissues or fluids because the sterility and functionality of these devices cannot be assured.

Specifications

Table 9 shows the eCoin physical specifications. For detailed descriptions and specifications for other components, such as the external controller, refer to the product literature packaged with those devices.

Table 9: eCoin Specifications

Physical Attributes	Thickness	3.2 mm
	Diameter	23.3 mm
	Weight	2.9 grams
	Volume	1.36 cc
Stimulation Characteristics	Frequency	20 Hz (fixed)
	Pulse Width	200 µs (fixed)
	Amplitude	0.5, 1-15 mA (current regulated)
	Amplitude Step Size	0.5 mA (0.5 to 1 mA) 1 mA (1 mA to 15 mA)
	Session Duration	30 minutes (fixed)
	Session Interval	3 Days – First 42 Sessions (up to 18 weeks) 4 Days – All Sessions Thereafter
Power Source	Battery Life	1-8 years
	Power Source	75 mAh (3 V)

Note: All dimensions are approximate.
* Battery life estimated at minimum (1 mA: 8 years), moderate (6 mA: 3-5 years), and device maximum (15 mA: 1 year) stimulation settings.

Table 10 shows the materials used in the eCoin package that come in contact with human tissue.

Table 10: 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.

Table 11 shows the Patient Controller specifications.

Table 11: Patient Controller Specifications

Components	Magnet	
	Silicone Sleeve	
	Paper Tape	
Materials	Magnet	Nickel-Copper
	Silicone Sleeve	Clear Silpuran 8020/70
	Paper Tape	Paper (latex-free)

eCoin Implant Procedure

The following section describes the procedure for implant of the eCoin Peripheral Neurostimulator.

Clinician Training

Implanting Clinicians should be trained and certified by Valencia Technologies on the implantation and use of the eCoin Peripheral Neurostimulator System.

Pre-procedure Information

eCoin device implantation is unilateral. Choice of leg will be determined by the implanting physician and patient.

The procedure can be performed in a clinic procedure room or operating room. There should be appropriate lighting. A headlamp is useful, but not mandatory.

Procedure Supplies

The following supplies are needed for the preparation and implantation of the eCoin.

- eCoin Device Kit
- eCoin Surgical Kit (not required, but highly suggested; if not utilized, implanting physician to provide all tools and equipment)
- Local anesthetic (provided by implanting physician), usually 10-20 mL are needed. Suggested options:
    - 0.25% bupivacaine with 1:200K epi (2.5 mg/kg OR 1 cc/kg)
    - 0.5% bupivacaine with 1:200K epi (2.5 mg/kg OR 0.5 cc/kg)
    - 1% lidocaine with 1:200K epi (7 mg/kg OR 0.7 cc/kg)
- Sterile gloves (provided by implanting physician, minimum of 2 pairs per person performing or assisting with procedure)

A battery-powered electrosurgery device (provided by implanting physician) can be useful for hemostasis during the procedure but is not mandatory. CAUTION:

The eCoin device may be damaged by exposure to current from electrosurgery. Electrosurgery should not be used while the eCoin device is in the body.

An eCoin Surgical Kit containing the majority of the items needed for implant is utilized with the eCoin Device Kit. These items include common surgical tools (**Figure 4a and 4b**), two custom instruments (**Figure 5**), sterile drape, syringes and needles used for local anesthetic injection, antiseptic prep solution, sterile OR towels, surgical gown, saline flushes, absorbable sutures, Dermabond (skin glue), and a waterproof bandage.

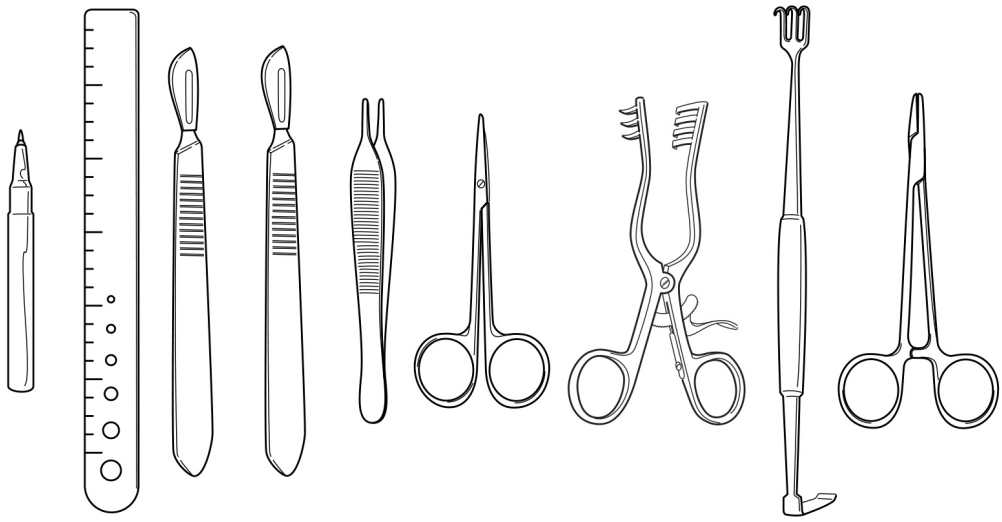


Figure 4a: Common tools (left to right) used for the procedure: surgical marking pen, ruler, 15 blade scalpel, toothed forceps, dissecting scissors, small self-retaining retractor, double-ended skin retractor, needle driver.

Figure 4b. 15 blade scalpel profile. Scalpel blades included in the kit are No. 15. If physician chooses not to use the eCoin Surgical Kit, it is highly recommended that No. 15 scalpel blades are used for the implant procedure.

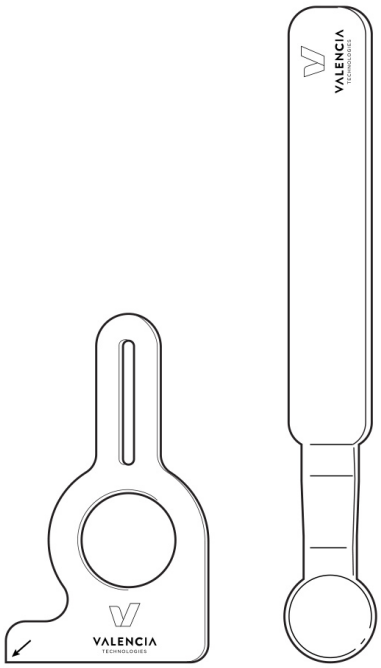


Figure 5: Custom instruments (left to right): marking template and pocket creation tool.

Anatomy

In the lower leg, the tibial nerve courses between the heads of the gastrocnemius muscles before emerging from beneath the soleus muscle and flexor digitorum longus muscles.

Just above the ankle, the tibial nerve runs anterior to the Achilles tendon and posterior to the medial malleolus and the flexor digitorum longus tendon, before diving under the flexor retinaculum as it enters the tarsal tunnel (**Figures 6 and 7**).

The device is placed at a location in the medial lower leg where the tibial nerve is most superficial, and where contact with the medial malleolus is avoided (**Figures 8 and 9**).

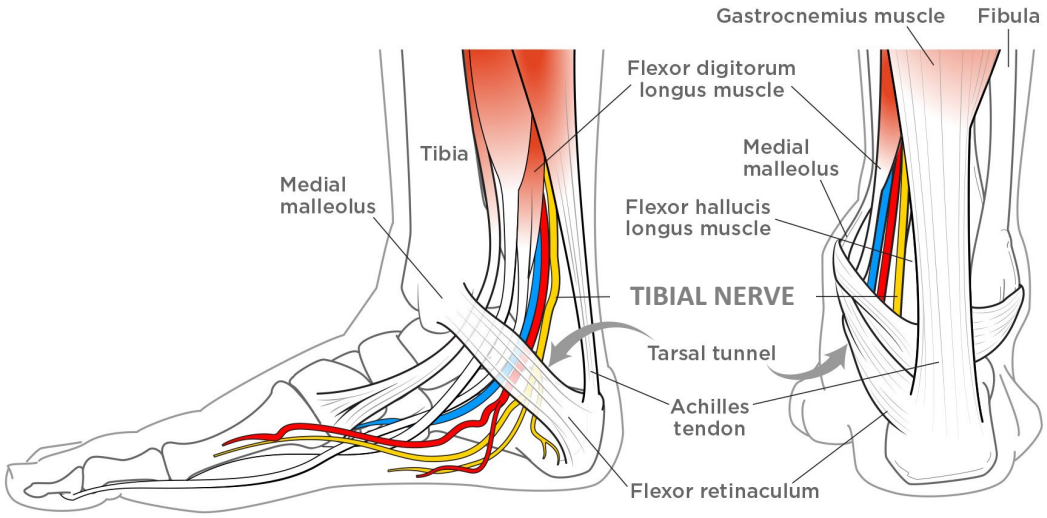


Figure 6: Medial and posterior views of right foot

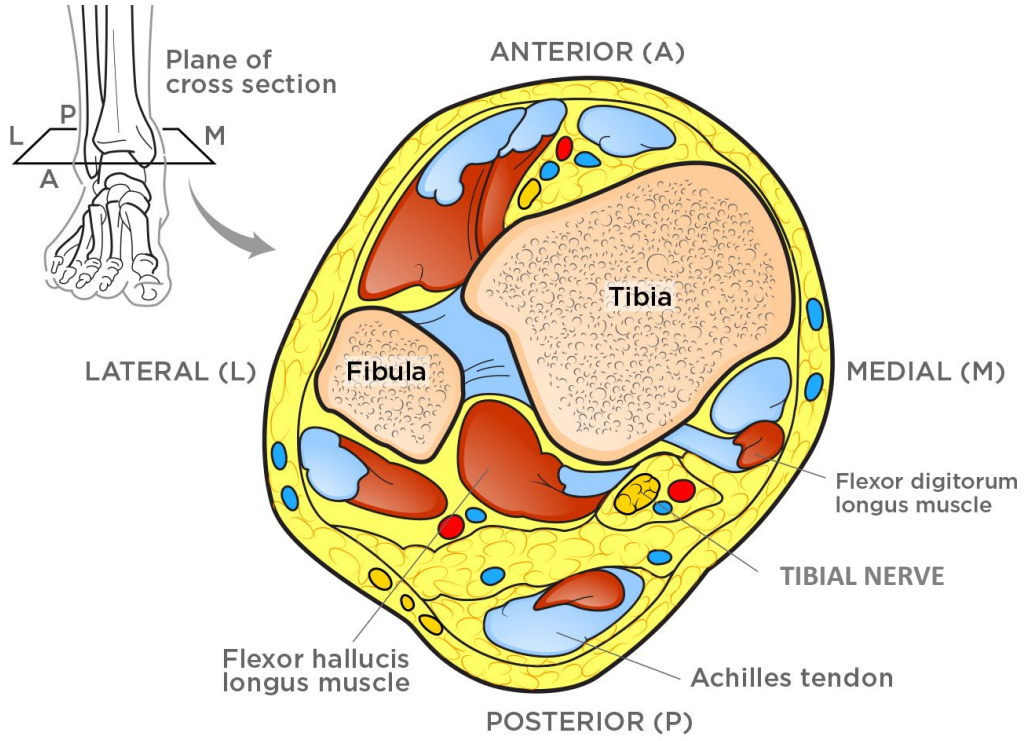


Figure 7: Axial view of right ankle

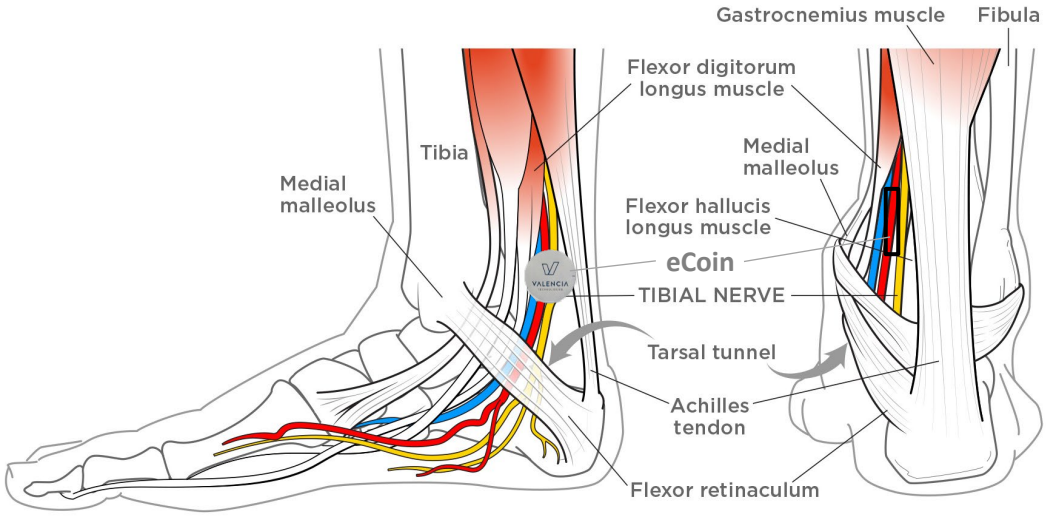


Figure 8: Medial and posterior views of right foot with eCoin in place. NOTE: image is not to scale.

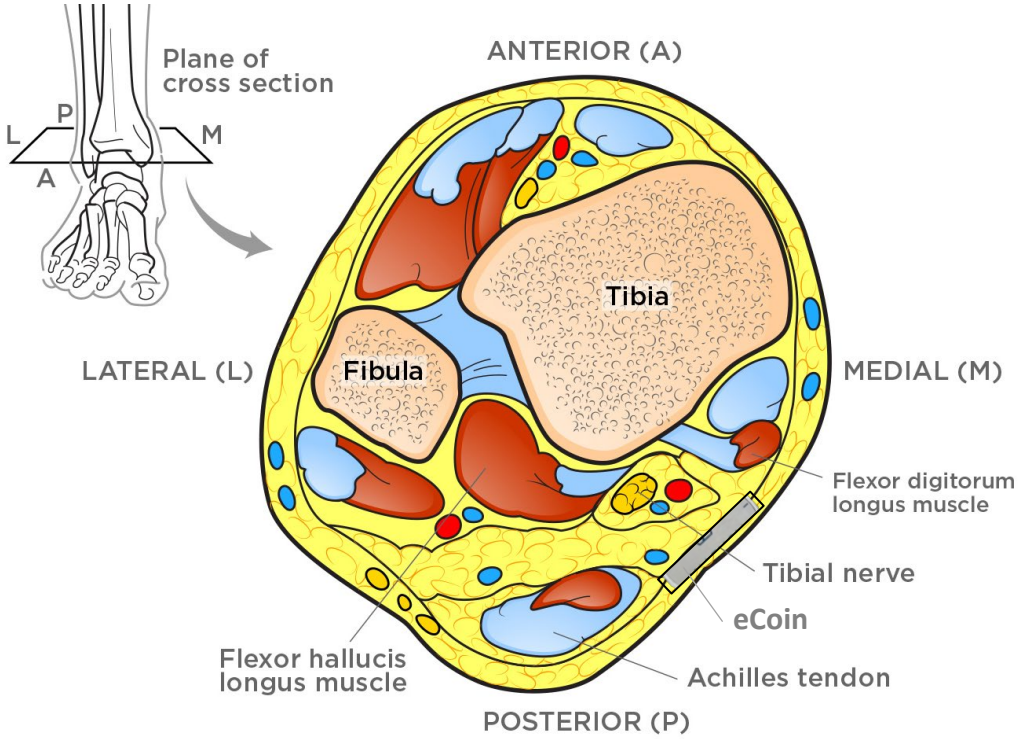


Figure 9: Axial view of right ankle with eCoin in place. NOTE: image is not to scale.

eCoin Implantation Procedure

The procedure steps are as follows:

1) Position and prepare patient
2) Mark implant location
3) Inject local anesthetic
4) Sterile prep and drape
5) Make incision and create device pocket
6) Insert device into pocket
7) Close incision in layered fashion, apply dressing
8) Apply ankle support
9) Provide aftercare instructions

1. Position and Prepare Patient

Position the patient on the procedure table. The medial ankle and medial malleolus surface of the selected leg should be facing up towards the ceiling. Remove shoes, socks, and trousers. Trim any hair near the ankle. Clear a wide area around the foot and ankle.

Suggestions for positioning the patient:

- Supine position: selected leg externally rotated so medial ankle faces the ceiling, toes pointing toward surgeon's non-dominant hand.
- Scissor position: patient tilted towards the same side as selected leg, selected leg flexed at knee and brought back, opposite leg extended forward, out of the way.

2. Mark Implant Location

Surface markings are made to guide the administration of local anesthetic.

A. The leg and foot should be flat on the table. Ankle should be placed at neutral (sole of the foot perpendicular to lower leg, so ankle is at 90 degrees).

B. Palpate and mark the anterior and posterior borders of the medial malleolus using one of the skin markers included in the eCoin Surgical Kit. Mark the midpoint between the borders along the diameter of the malleolus. This malleolar midpoint will be the main reference point.

C. With the ankle at neutral, position the bottom corner (pointed arrow) of the Valencia marking template to coincide with the midpoint of the medial malleolus. (NOTE: There are two marking templates included in the eCoin Surgical Kit. One is intended to be used in this step in a non-sterile fashion. Once this template is used non-sterilely, discard the template.) The bottom edge of the template should be horizontal and parallel to the sole of the foot. The long slot should be parallel to the Achilles tendon. Hold the template in position and use a surgical marking pen to draw a circle along the inner edge of the circular opening. This circle indicates the surface projection of the eCoin device position. Mark a line through the template slot. This line indicates the planned incision

(**Figure 10**). See **Figure 11** for an illustration of the final markings with dimensions.
NOTE: The template can be used for either leg simply by reversing it.

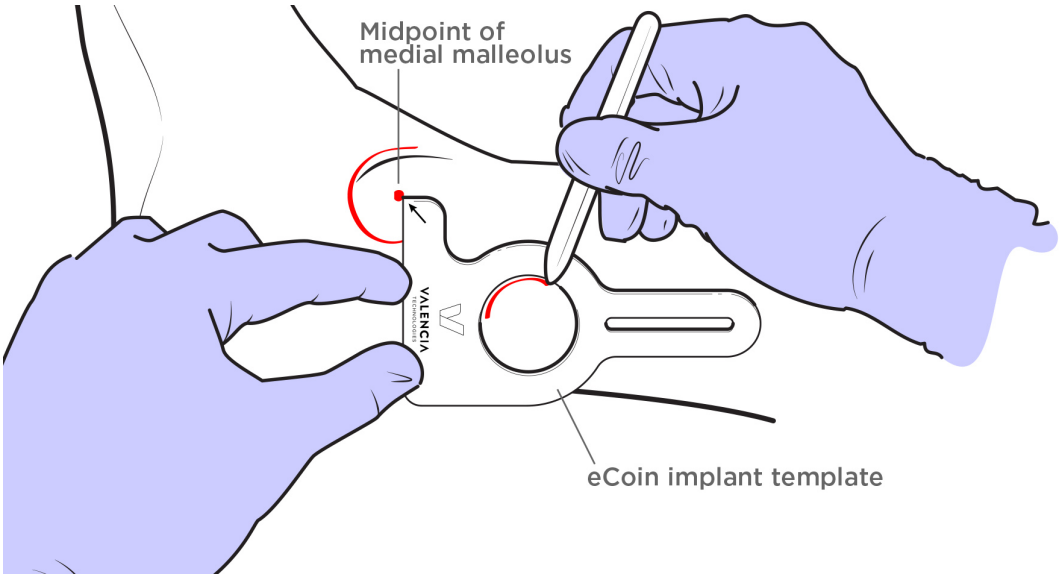


Figure 10: Marking the area using the template. Ensure the template slot is parallel to the Achilles tendon and not angled toward the tendon.

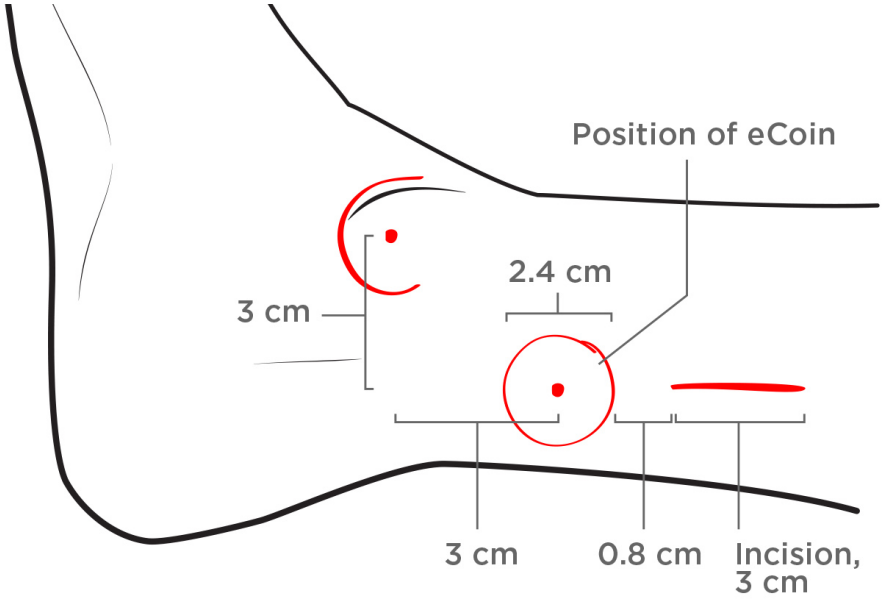


Figure 11: Marking overview, with dimensions.

3. Inject Local Anesthetic

Cleanse the anticipated injection sites on the skin with isopropyl alcohol swabs or 1 mL ChloraPrep swab included in the Surgical Kit, taking care not to wipe away the markings entirely. Using one of the included 25-gauge needles, generously infiltrate local anesthetic subcutaneously into the leg, including the incision site *and* the device implant location; typically, 10-20 mL of local anesthetic is needed. The tibial nerve and deep subfascial tissues should not be infiltrated with anesthetic. To decrease bleeding during implant placement, **local anesthetic with epinephrine** is highly recommended.

The treated area should generously include the planned incision, the planned device location, and interval areas. After injection, massage the area to promote diffusion of the anesthetic into the surrounding tissues.

4. Sterile Preparation and Draping of Surgical Area

With the patient's help, lift the foot and lower leg in the air. Working from top to bottom, circumferentially prep the lower leg, ankle, and foot with the included 26 mL ChloraPrep solution. The prepped forefoot including the toes and the calf should be wrapped with sterile towels and secured with the included towel clamps. Apply the provided drape by bringing the foot through the fenestration. to create the sterile field. The entire foot, ankle, and distal calf will be in the field using the drape. Surgical markings may come off during prepping; the markings will be redrawn in the next step.

5. Make Incision and Create Implant Pocket

A. Use the second sterile Valencia template and second sterile skin marker to remark the circular opening and vertical slot. (NOTE: Do not re-use the same nonsterile template and skin marker from Step 2.)

Confirm appropriate positioning of the ankle and template location:

- Keep the ankle at 90 degrees
- Position the bottom corner of the template to coincide with the midpoint of the medial malleolus
- Bottom edge of the template should be parallel to the sole of the foot
- Slot should be parallel to the Achilles tendon

B. Make the incision through the skin and dermis with the provided scalpel on the marked longitudinal incision line (**Figure 12**).

For patients with thicker subcutaneous tissue, the incision may need to be lengthened in order to permit implant insertion. In this situation, extend the incision proximally (towards knee, not towards foot).

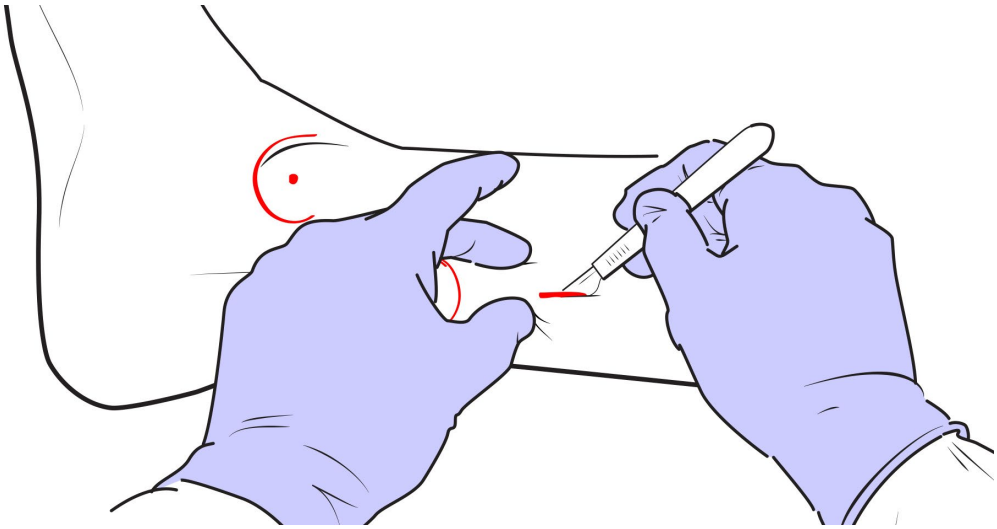


Figure 12: Making the incision

C. Using dissecting scissors, gently and bluntly dissect vertically thru the subcutaneous tissue. Expose the surface of the fascia layer, which is white in color and has transverse fibers. The fascia can be visualized further by blunt dissection with a finger and gauze to clear adherent fat on the fascia.

It is very important at this step to identify the fascia layer and not violate it with the scissors. Any fascial violation must be recognized, and dissection redirected above the fascia to create the proper plane. Dissection must not be carried deep to the fascia as there is risk of injury to deep structures such as nerves, vessels, and tendons.

Using the scissors, create a small distal 2mm pocket in the plane between the subcutaneous fat and the fascia.

D. Use the provided pocket creation tool (**Figure 5**) to create the implant pocket above the fascia. Position the round end of the tool in the wound, just above the

fascia. It is critical that the tool sit directly on the fascia and not below the fascia, through a violation. Push the tool toward the marked circle until its rounded end coincides with the marked circle on the overlying skin. Keep a finger at the distal edge of the marked circle when pushing the tool to limit the travel of the tool and prevent overshooting of the planned implant position (**Figure 13**). The pocket creation tool should travel in a straight line towards the heel. The tool may be withdrawn partially and pushed forward again if additional force is needed to create the pocket. Withdraw the tool from the pocket.

Do NOT move the tool side-to-side while pushing. Keep the tool level during use. Use the finger as a "stop" to prevent tool from travelling too far. If the tool is moved side to side or travels too far, the pocket will be oversized which will result in implant migration/movement.

Failing to reach the fascia layer and pocket creation within the subcutaneous tissue will increase the distance between the eCoin and the tibial nerve. This increased distance can increase the required amplitude setting for therapy. If there is adipose tissue between the implant pocket and the fascia layer, this can decrease the strength of the stimulation delivered to the tibial nerve.

The implant pocket should lie directly above the fascia layer. The implant pocket should not be created below the fascia layer. Dissection and pocket creation below the fascia risks injury to deep structures and can cause nerve contusion, neuritis, pain, vessel injury and bleeding, and tendonitis.

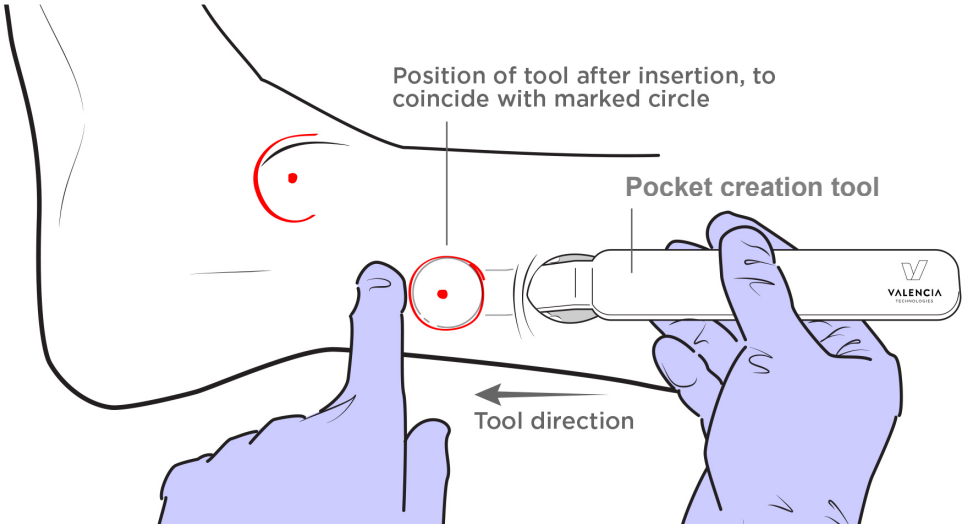


Figure 13: Creating the implant pocket using the pocket creation tool

E. Obtain hemostasis with manual pressure, or with cautery (rare). Generously irrigate pocket with the provided normal saline. Note: To ensure that the eCoin device does not experience irreversible changes to its function, only use electrosurgery before the device has been inserted. After insertion, keep electrosurgery no closer than 25 cm from the device.

6. Insert Device into Pocket

A. ***The surgeon should change to a new pair of sterile gloves before handling the eCoin device.***

B. An assistant should open the eCoin device packaging box, take out the packaging tray, and carefully peel the outer Tyvek lid off. Remove the inner tray in sterile fashion. Peel open the inner Tyvek lid and remove the retainer.

Note: The eCoin Surgical Kit includes two scalpel blades. The intended use for the second blade is to assist in opening the eCoin device packaging as needed.

C. Remove the eCoin device from the inner tray in a sterile fashion and grasp it manually. *The eCoin device should never be grasped with a metal instrument.*

D. Tilt the eCoin device approximately 45 degrees and insert into the incision opening. Rotate the device to horizontal position. If necessary, elevate the distal skin with a retractor to facilitate device placement. *Ensure that the Valencia logo and text on the eCoin surface is facing up. If the eCoin is inserted upside down, it will fail to stimulate the tibial nerve.*

E. Place a finger at the distal edge of the marked circle on the skin. This finger will serve as a backstop during device positioning. Manually slide the device caudally on top of the fascia until it is centered at the marked circle on the skin (**Figure 14**).

Small vertical tissue bands connecting the fascia to the skin may need to be separated to properly position the eCoin. Bluntly divide these remaining bands with the pocket creation tool, if needed.

Double check again that the electrode side of the device (the side with the cathode disk and without a logo) is facing down towards the tibial nerve and that the "Valencia" logo and text is facing up.

Following proper pocket creation and device insertion, the device's posterior edge should not impinge on the medial edge of the Achilles tendon when palpated.

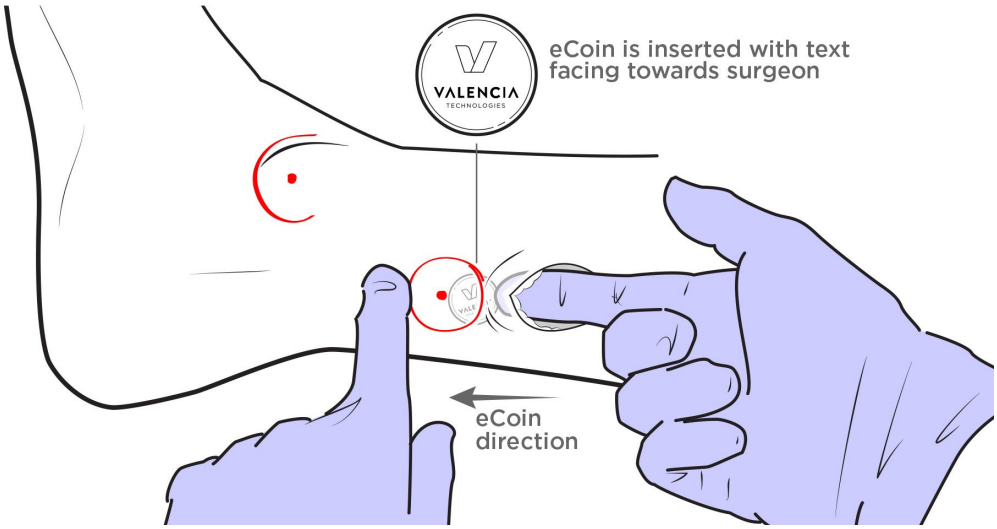


Figure 14: Inserting the eCoin device.

7. Close Incision in Layered Fashion, Apply Dressing

A. To prevent proximal implant migration, an internal absorbable stitch should be placed to anchor the subcutaneous fat layer down to the fascia, at a location just proximal to the implant. This stitch should be performed at the upper edge of the device outline. A partial-thickness fascial suture bite is advised. Do not penetrate through the full thickness of the fascia, so as to avoid injury to underlying neurovascular structures.

B. Irrigate the wound with included normal saline.

C. Close the incision in layered fashion, making sure to obliterate dead space in the deeper layers. (**Figure 15**). Close with minimal knot burden and handle all tissues gently. Do not crush the skin with the forceps while sewing. Suggested closure (sutures provided in Surgical Kit):

Subcutaneous layer: 3-0 Vicryl inverted sutures
Deep dermis layer: 3-0 Vicryl or Monocryl inverted sutures
Subcuticular layer: Running 4-0 Monocryl suture

If the epidermis/dermis is thin and/or fragile and hard to close, an alternate closure can be performed using 3-0 nylon interrupted, non-strangulating horizontal mattress sutures which are removed at the 2-week visit.

D. Apply provided skin glue (Dermabond).

Dermabond is not used with a nylon suture closure.

E. Apply provided waterproof bandage.

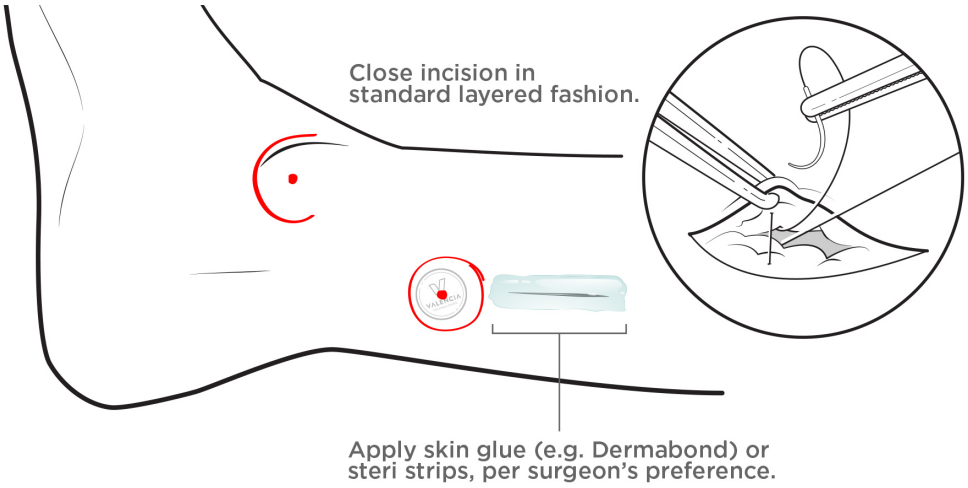


Figure 15: Closing the incision

8. Apply Ankle Support

The patient will be provided with a compressive ankle support to be worn. The ankle support serves to cushion and protect the incision while it heals and limit ankle motion which helps prevent device migration during the healing phase.

Use a properly sized ankle support: it should be snug and comfortable, not tight. Utilize the sizing chart that comes with the ankle support. The support should be

applied smoothly, without wrinkles. The ankle support should be used until the first post-procedure clinic visit, and possibly longer, per surgeon's discretion.

9. Provide Aftercare Instructions

A. Device registration form should be completed, and implant card detached and provided to patient.

B. Postoperative analgesia, as needed.

C. Avoid vigorous/strenuous activity and exercise for 8 weeks. Ordinary walking is acceptable. No running or bicycling.

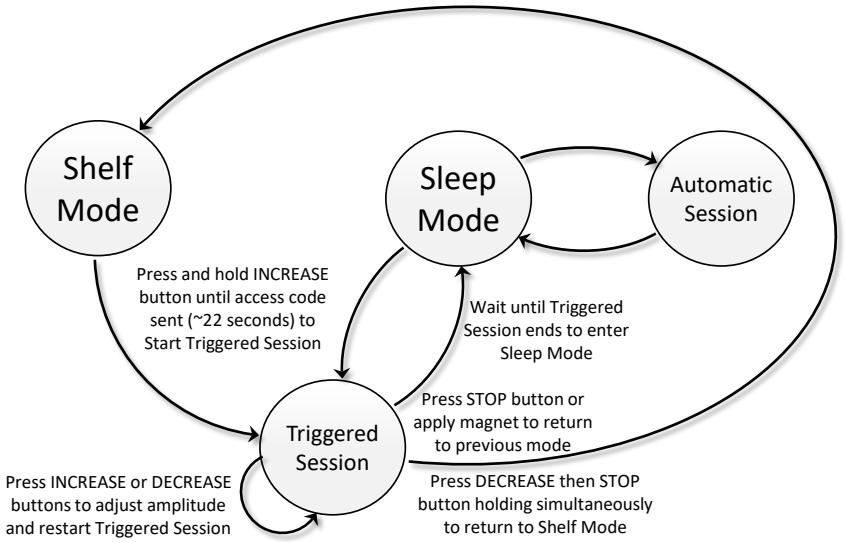
D. Slight bruising and swelling is normal for 1-2 weeks.

E. Patients should not wear shoes that impinge on the device edge. The tops of shoes should either end well above or well below the device.

F. The incision should be kept covered and dry until the first post-procedure clinic visit. A shower bag is included with the patient's aftercare materials.

NOTE: Written post-procedure instructions to be provided by Valencia.

eCoin Device Activation and Reprogramming



Following a short incision healing period, the patient's device will be activated by a Technically Trained Field Person. During this initial programming, the eCoin device will transition from Shelf Mode to a Triggered Session, wherein the Field Person will adjust the stimulation amplitude to a comfortable level for the patient. Upon completion of the first 30-minute stimulation session, the eCoin device will enter sleep mode. From there, the eCoin device will undergo a 30-minute Automatic Session of stimulation according to the following schedule:

Session Interval	Session Duration
Every 3 days starting from 1st stimulation session for up to 18 weeks (42 sessions)	30 minutes
Every 4 days from previous stimulation session thereafter	30 minutes

The Technically Trained Field Person is thoroughly trained on how to use the External Controller to activate and program the eCoin device. An eCoin Technical Programming Manual is provided with extensive instructions for safe and effective use of the eCoin system. Treating physicians, or a member of their staff, will be able to program the eCoin system after completing the appropriate additional training and certification process.

The battery-life expectancy of the eCoin device is dependent on the programmed stimulation amplitude. During the activation visit, the Technically Trained Field Person will provide a Battery Life Form that contains the expected battery life and depletion date. The information from this form allows for adequate time to prepare for and schedule eCoin device explant.

The eCoin device can be reprogrammed at any time by the Technically Trained Field Person to increase or decrease the stimulation amplitude if necessary. In this case, the Field Person will provide an updated Battery Life Form, which will contain the revised eCoin device battery depletion date.

eCoin Removal/Replacement Procedure

Removal of the eCoin is very similar to its placement. The procedure steps are as follows:

1) Position and prepare patient
2) Mark existing device location and incision scar
3) Inject local anesthetic
4) Sterile prep and drape
5) Make incision and dissect toward device pocket
6) Remove device from pocket, reinsert device if needed
7) Close incision in layered fashion, apply dressing
8) Apply ankle support
9) Provide aftercare instructions

In cases where the device is explanted and the replacement device is implanted in the opposite leg, follow the instructions below for removal and refer back to the implantation instructions above for the replacement.

It is not recommended that physicians re-implant in a previously explanted and healed site.

1. Position and Prepare Patient

Position the patient on the procedure table. The medial ankle and medial malleolus surface of the selected leg should be facing up towards the ceiling. Remove shoes, socks, and trousers. Trim any hair near the ankle. Clear a wide area around the foot and ankle.

2. Mark Existing Device Location and Incision Scar

A. The leg and foot should be flat on the table. Ankle should be placed at neutral (sole of the foot perpendicular to lower leg, so ankle is at 90 degrees).

B. Palpate and mark the anterior and posterior borders of the medial malleolus using one of the skin markers included in the eCoin Surgical Kit. Mark the midpoint between the borders along the diameter of the malleolus. This malleolar midpoint will be the main reference point.

C. Palpate the region posterior and superior to the medial malleolus. Palpate the existing eCoin device and mark a circle around it on the skin surface.

*D. In order to prevent incisional healing or skin necrosis problems, it is important to identify and utilize the previous scar. Do not create a new, parallel incision. Mark the existing, visible longitudinal incision scar (**Figure 16**).*

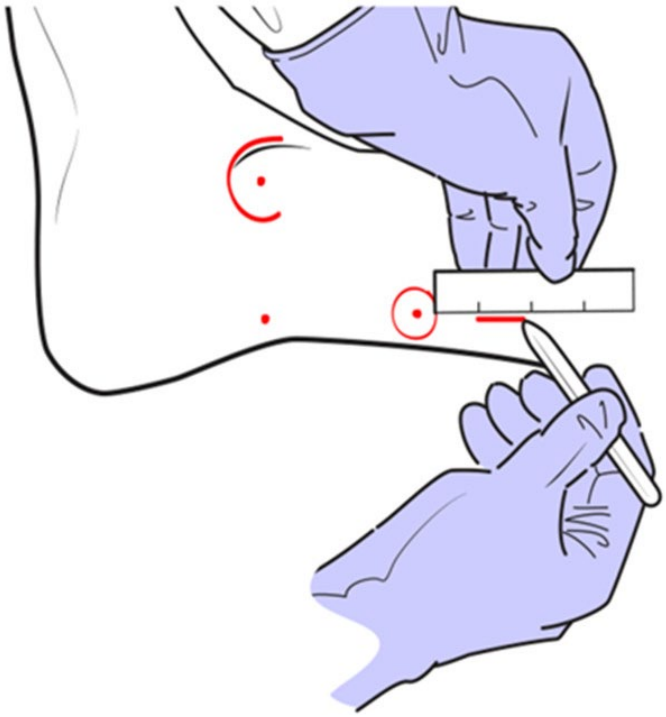


Figure 16: Marking the existing incisional scar

E. ***If the device is not readily palpable***, the Valencia template can be used to identify the device location. With the ankle at neutral, position the bottom corner (pointed arrow) of the Valencia marking template to coincide with the midpoint of the medial malleolus. Align the existing incision scar in the narrow template slot. Mark the scar if not already done (**Figures 17 and 18**). *Do not create a new, parallel incision*. Use the surgical marking pen to draw a circle along the inner edge of the circular opening. This circle should correspond to the surface projection of the eCoin device.

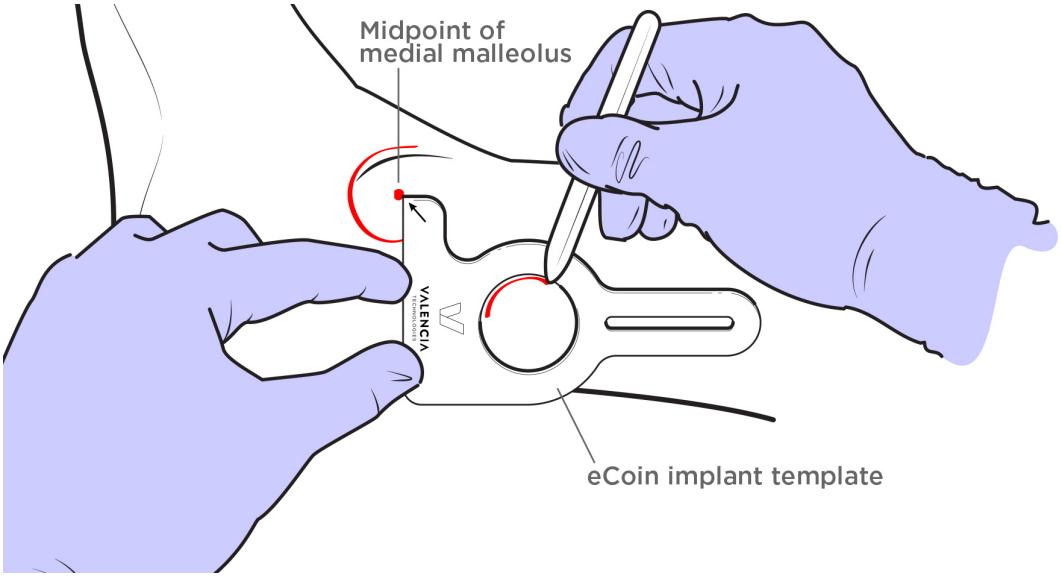


Figure 17: Marking the area using the template

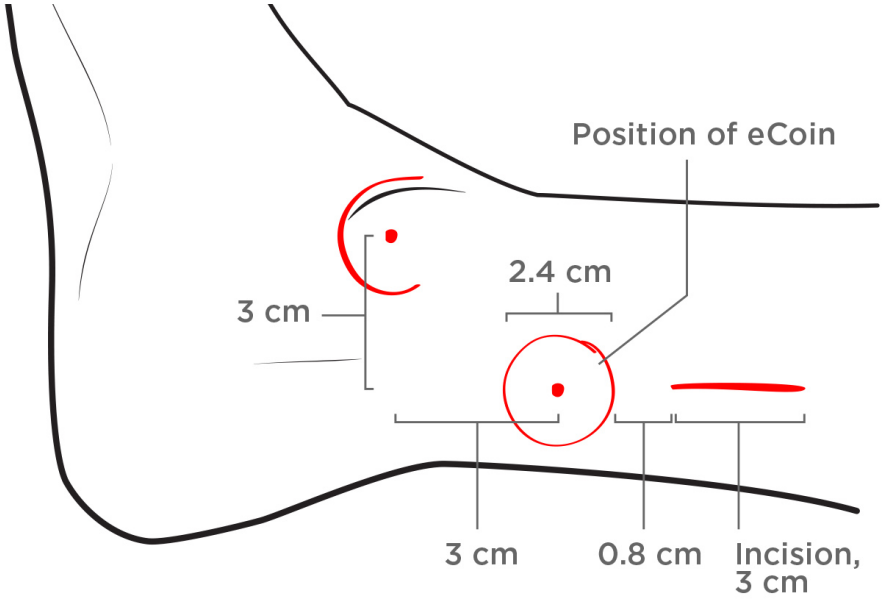


Figure 18: Marking overview, with dimensions.

3. Inject Local Anesthetic

Cleanse the anticipated injection sites on the skin with the included isopropyl alcohol swabs or 1 mL ChloraPrep swab, taking care not to wipe away the markings entirely. Using a 25-gauge needle, generously infiltrate local anesthetic subcutaneously into the leg, including the incision site *and* the device implant location; typically, 10-20 mL of local anesthetic is needed. The tibial nerve and deep subfascial tissues should not be infiltrated with anesthetic. To decrease bleeding during implant placement, **local anesthetic with epinephrine** is highly recommended.

The treated area should generously include the planned incision, the existing device location, and interval areas. Care should be taken to not puncture the existing eCoin device in the pocket. After injection, massage the area to promote diffusion of the anesthetic into the surrounding tissues.

4. Sterile Preparation and Draping

With the patient's help, lift the foot and lower leg in the air. Working from top to bottom, circumferentially prep the lower leg, ankle, and entire foot with the included 26 mL ChloraPrep solution. The prepped forefoot including the toes and the calf should be wrapped with sterile towels and secured with the included towel clamps. Apply the provided drape by bringing the foot through the fenestration. to create the sterile field. The entire foot, ankle, and distal calf will be in the field using the drape. Surgical markings may come off during prepping; the markings will be redrawn in the next step.

5. Make Incision and Dissect Toward Device

NOTE: The pocket creation tool is not used during this procedure.

A. If needed, use a sterile Valencia template and sterile skin marker to remark the circular opening and prior scar.

B. Reopen the marked medial calf scar through the skin and dermis with the provided scalpel along the marked longitudinal incision line.

For patients with thicker subcutaneous tissue, the incision may need to be lengthened, in order to permit exposure. In this situation, extend the incision proximally (towards knee, not towards foot).

C. Using dissecting scissors, gently and bluntly dissect vertically thru the subcutaneous tissue. Scar tissue may be encountered. Expose the surface of the fascia layer. The fascia can be visualized further by blunt dissection with a finger and gauze to clear adherent fat on the fascia. Continue blunt dissection in the caudal direction with the scissors. Blunt dissection should be performed in the plane between the subcutaneous fat and the deep fascia. Do not violate or dissect through the fascia.

D. After blunt dissection approaches the device, it will be necessary to identify the implant capsule (the scar tissue around the device). Bluntly dissect into the capsule. Often, it will be necessary to grasp the capsule, cut it open with the scissors, then open it transversely. Visualize the device.

6. Remove Device from Pocket, Reimplant Device if Needed

A. Grasp the device with a forceps or clamp and extract. Additional blunt spreading may be necessary to extract the device. Elevate the adjacent skin with skin hooks or a retractor to facilitate device removal.

B. Obtain hemostasis with manual pressure, or with cautery (rare). Generously irrigate pocket with the provided normal saline.

For device removal only: skip the remainder of Step 6 and proceed to Step 7. For device reimplant: complete remainder of Step 6 and then proceed to Step 7.

C. ***The surgeon should change to a new pair of sterile gloves before handling the eCoin device.***

D. An assistant should open the eCoin device packaging box, take out the packaging tray.

E. Remove the eCoin device from the inner tray in a sterile fashion and grasp it manually. *The eCoin device should never be grasped with a metal instrument.*

F. Tilt the eCoin device approximately 45 degrees and insert into the incision opening. Rotate the device to horizontal position. If necessary, elevate the distal skin with a retractor to facilitate device placement. *Ensure that the Valencia logo and text on the eCoin surface is facing up. The electrode side of the device (the side with the cathode disk and without a logo) should be facing down towards the tibial nerve.*

G. Manually slide the device caudally and reinsert into existing pocket.

7. Close Incision in Layered Fashion, Apply Dressing

A. To prevent proximal implant migration, an internal absorbable stitch should be placed to anchor the subcutaneous fat layer down to the fascia, at a location just proximal to the implant. This stitch should be performed at the upper edge of the device outline. A partial-thickness fascial suture bite is advised. Do not penetrate through the full thickness of the fascia, so as to avoid injury to underlying neurovascular structures.

B. Irrigate the wound with included normal saline.

C. Close the incision in layered fashion, making sure to obliterate dead space in the deeper layers (**Figure 19**). Close with minimal knot burden and handle all tissues gently. Do not crush the skin with the forceps while sewing. Suggested closure (sutures provided in Surgical Kit):

Subcutaneous layer: 3-0 Vicryl inverted sutures
Deep dermis layer: 3-0 Vicryl or Monocryl inverted sutures
Subcuticular layer: Running 4-0 Monocryl suture

If the epidermis/dermis is thin and/or fragile and hard to close, an alternate closure can be performed using 3-0 nylon interrupted, non-strangulating horizontal mattress sutures which are removed at the 2-week visit.

D. Apply provided skin glue (Dermabond).

Dermabond is not used with a nylon suture closure.

E. Apply provided waterproof bandage.

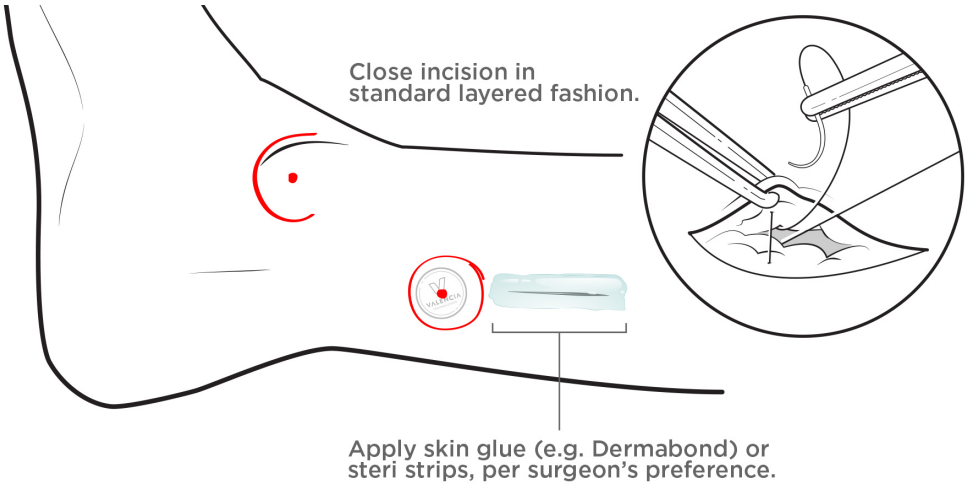


Figure 19: Closing the incision

8. Apply Ankle Support

The patient will be provided with a compressive ankle support to be worn. The ankle support serves to cushion and protect the incision while it heals and limit ankle motion which helps prevent device migration during the healing phase.

Use a properly sized ankle support; it should be snug and comfortable, not tight. Utilize the sizing chart that comes with the ankle support. The support should be applied smoothly, without wrinkles. The ankle support should be used until the first post-procedure clinic visit, and possibly longer, per surgeon's discretion.

9. Provide Aftercare Instructions

A. Device registration form should be completed, and implant card detached and provided to patient.

B. Postoperative analgesia, as needed.

C. Avoid vigorous/strenuous activity and exercise for 8 weeks. Ordinary walking is acceptable. No running or bicycling.

D. Slight bruising and swelling is normal for 1-2 weeks.

E. Patients should not wear shoes that impinge on the device edge. The tops of shoes should either end well above or well below the device.

F. The incision should be kept covered and dry until the first post-procedure clinic visit. A shower bag is included with the patient's aftercare materials.

NOTE: Written post-procedure instructions to be provided by Valencia.

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. For more information, go to www.P65Warnings.ca.gov.

Customer Service

For questions regarding the eCoin Peripheral Neurostimulator System, additional information, and product manuals, visit our website:
www.eCoin.us
or call:
Tel: +1-833-ECOIN-US or 833-326-4687

For all warranty information, refer to:
www.eCoin.us/warranty