

Category

Best Medical Technology

Drug / Device Name

eCoin® Tibial Neurostimulator

Compound/ Tech Name

eCoin® Tibial Neurostimulator

Trade Name

eCoin® Tibial Neurostimulator

Date of Approval

2022-03-01

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.

Therapeutic Categories

Implantable Neurostimulator Device

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.

Attached Files:

- eCoinPatientManualP200036C.pdf

Background information and need for drug/device

Incumbent neuromodulation solutions are invasive and costly and require large amount of resources to implant, program and maintain. Alternatively, medications used to treat UUI symptoms are often costly or have undesired side-effects. eCoin represents the newest and most innovative way to provide years of lasting relief from UUI symptoms and is implanted during a brief procedure by a trained physician.

History of the development of the drug/device

Valencia Technologies was founded in 2010 by Jeff Greiner - an accomplished business leader and executive officer in the medical device industry. Prior to founding Valencia Technologies in 2010, he led Advanced Bionics, where in his 18 years with the firm he rose from chief operating officer to president to chief executive officer. Jeffrey Greiner played a key role in taking Advanced Bionics from its spin-off

stage to a 300 million-dollar operation specializing in creating devices that allow deaf people around the world to hear. In addition, he eventually oversaw the split-up and multibillion-dollar sale of the company, which today is owned by the firms of Boston Scientific and Sonova.

For the eCoin device, Valencia conducted a feasibility study on 48 patients in the U.S. and New Zealand and that data has been published by the Journal of Urology. (Attached). With 70% of patients improving in their urgency urinary incontinence by at least 50% and nearly a quarter of patients completely dry in their symptoms, eCoin demonstrated excellent effectiveness results. Furthermore, the eCoin device—implanted in the lower leg in a 15 minute office procedure—appears to have a benign safety profile in stark contrast to sacral neuromodulation.

Valencia currently has more than thirty issued patents for its innovative ideas around eCoin and neurostimulation.

Attached Files:

- Pivotal Study of Leadless Tibial Nerve Stimulation with eCoin for Urgency Urinary Incontinence_ An OpenLabel Single Arm Trial.pdf

Why this drug or device is innovative, the broad implications for future research, and/or how it will improve the human condition

eCoin is a small neurostimulator device that is currently available for effectively and safely treating bladder dysfunction.

Neurostimulators have emerged as pioneering treatments for various nervous system disorders, from chronic back pain to paralysis—yet, few are as versatile as the eCoin device. eCoin is small, easy-to-implant and has a long-lasting battery. It has a forgiving dome-shaped stimulation field that makes placement of the device simple for the implanting surgeon. eCoin is significantly changing the landscape of bladder control and leakage therapy. It will only take a few years for this technology to be adapted to other stimulation locations on the body to treat many other conditions.

Please provide appropriate references (ie Pubmed links)

Pivotal Study of Leadless Tibial Nerve Stimulation with eCoin® for Urgency Urinary Incontinence: An Open-Label, Single Arm Trial - PUBMED
<https://pubmed.ncbi.nlm.nih.gov/33797291/>