

FDA Approved EMF Devices

Percutaneous Electrical Nerve Field Stimulation (PENFS)

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"A percutaneous electrical nerve field stimulator device is comprised of a disposable battery-operated stimulator that is worn behind the ear and connected to stimulation needles that are positioned along branches of the occipital and cranial nerves. Unlike other electrical stimulation methods that focus on specific nerves, the percutaneous electrical nerve field stimulator targets a broader area, including multiple nerves and brain regions involved in processing pain."

Source:

https://www.anthem.com/medpolicies/abc/active/gl_pw_f008543.html#:~:text=A%20percutaneous%20electrical%20nerve%20field%20stimulator%20device,branches%20of%20the%20occipital%20and%20cranial%20nerves

1. P-Stim is a single-use, miniature, battery-powered auricular electroacupuncture device that delivers low-frequency electrical stimulation to auricular acupuncture points via connected needles for use in the practice of acupuncture.

"P-STIM is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states."

"The P-Stim is intended for use as an electro-acupuncture device to stimulate appropriate auricular acupuncture points."

"The P-Stim is a miniaturized, battery-powered, transcutaneous electrical nerve stimulator that has a pre-programmed frequency, pulse, and duration for the stimulation of auricular acupuncture points."

"A selection stylus that measures electrical resistance is used to identify three auricular acupuncture points. The P-Stim device connects to three inserted acupuncture needles with caps and wires. The device is pre-programmed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours."

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K140788>

https://www.accessdata.fda.gov/cdrh_docs/pdf14/k140788.pdf

<https://www.bluecrossnc.com/providers/policies-guidelines-codes/commercial/therapy/updates/cranial-electrotherapy-stimulation-and-auricular-electrostimulation>

Manufacturer: Biegler GmbH, headquartered in Mauerbach, Austria (with U.S. distribution references). The applicant for FDA clearance was NeuroScience Therapy Corp.

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K140788>

https://www.accessdata.fda.gov/cdrh_docs/pdf5/k050123.pdf

Website: <https://www.biegler.com/>

Primary Indications: Indicated as an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states (not for specific disease claims).

"P-STIM is an electro-acupuncture device for use in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states."

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K140788>

https://www.accessdata.fda.gov/cdrh_docs/pdf14/k140788.pdf (summary)

Is it FDA Approved?: Yes, FDA-cleared (510(k) clearance as Class II device, product code BWK – Stimulator, Electro-Acupuncture).

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K140788>

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FDA Approval Details: Cleared via the 510(k) premarket notification pathway as a Class II device (substantially equivalent to predicate devices). Original Clearance (K050123): The foundational U.S. clearance for the P-Stim System was granted on March 30, 2006, under the applicant NeuroScience Therapy Corp.

Subsequent Clearance (K140788): As manufacturing and distribution rights shifted, a subsequent 510(k) clearance was granted to the manufacturer Biegler GmbH on June 27, 2014. Clearance based on substantial equivalence for use in acupuncture practice; no specific pain or disease indications cleared. The device is a pre-amendment type but cleared under 510(k).

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=k050123>

https://www.accessdata.fda.gov/cdrh_docs/pdf5/K050123.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K140788>

https://www.accessdata.fda.gov/cdrh_docs/pdf14/k140788.pdf

How It Works: The miniature, battery-powered unit connects to three auricular acupuncture needles (placed on the ear) and delivers pre-programmed low-frequency electrical stimulation (on for 180 minutes, off for 180 minutes) over up to 96 hours for auricular point stimulation.

"The P-Stim is a single-use miniaturized, battery-powered, low frequency transcutaneous electrical nerve stimulator with a pre-programmed frequency, pulse, and duration for the stimulation of auricular acupuncture points."

"Auricular electrostimulation involves the stimulation of acupuncture points on the ear... to provide ambulatory auricular electrical stimulation over a period of several days." It utilizes "ultrathin permanent needles" placed in the ear. "The stimulation pattern consists of 1 Hz single pulses with square waveform. The current direction is inverted every second pulse, which is intended to avoid polarization effects. To minimize the risk of adaption or tolerance to the electrical stimulation, stimulation is applied for 3 hours, followed by a pause of 3 hours."

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K140788>

https://www.accessdata.fda.gov/cdrh_docs/pdf14/k140788.pdf

<https://www.bluecrossnc.com/providers/policies-guidelines-codes/commercial/therapy/updates/cranial-electrotherapy-stimulation-and-auricular-electrostimulation>

Frequency Used: 1 Hz.

"The P-Stim produces 1 mA biphasic electrical impulses of 1 μ s duration with 1 Hz repetition frequency."

"Those in group EA [electroacupuncture] received continuous low-frequency EA using P-Stim™ (constant current: 1 Hz biphasic, 2 mA)... EA has been found to induce the release of various neurotransmitters such as enkephalin and dynorphins... in the central nervous system both in animal studies and in humans."

Sources:

https://warwick.ac.uk/fac/sci/eng/research/grouplist/sensorsanddevices/mbi/database/ieeesensors08/PDFs/Papers/045_6265.pdf

https://aurimod.com/site/assets/files/1223/sator-katzenschlager_et_al_2004.pdf

Is it Non-Thermal?: Yes. The therapy leverages low-level transcutaneous electrical pulses specifically to stimulate nerves at acupuncture points, exclusively utilizing electrical energy without generating or transferring thermal heat to the patient's tissues.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf5/k050123.pdf

Is it Non-Ionizing?: Yes. As a battery-powered "transcutaneous electrical nerve stimulator," it uses non-ionizing electrical impulses, presenting no risks associated with ionizing radiation such as X-rays or gamma rays.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf5/k050123.pdf

Side Effects: Generally well-tolerated with no device-related serious adverse events reported in clearance documentation or general use. Possible mild skin irritation at needle/electrode sites or temporary discomfort.

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Standard electrical stimulator warnings apply (e.g., do not use with cardiac pacemakers due to lack of clinical data). Contraindications include hemophilia and psoriasis vulgaris.

Because the device connects to "three inserted acupuncture needles" left in place for several days, it carries risks associated with percutaneous puncture, including minor bleeding, localized pain, or potential infection at the needle insertion sites. Additionally, patients may experience skin irritation or allergic reactions from the "self-adhesive electrode patch" used to affix the device behind the ear.

"No serious adverse events were reported."

Sources:

<https://www.biegler.com/en/notification-p-stim>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmnm.cfm?ID=K140788>

https://www.accessdata.fda.gov/cdrh_docs/pdf14/k140788.pdf

<https://www.bluecrossnc.com/providers/policies-guidelines-codes/commercial/therapy/updates/cranial-electrotherapy-stimulation-and-auricular-electrostimulation>

2. NSS-2 Bridge / Masimo Bridge: NSS-2 Bridge (rebranded as Masimo Bridge) is a prescription-only, non-invasive percutaneous nerve field stimulator (PNFS) device that delivers electrical pulses via needle arrays placed behind the ear to stimulate auricular branches of cranial nerves for reducing opioid withdrawal symptoms in adults.

"The NSS-2 Bridge is indicated for use to reduce the symptoms of opioid withdrawal."

"The NSS-2 Bridge is a small, battery-powered, percutaneous electrical nerve field stimulator (PENFS) that adheres to the skin behind the patient's ear and delivers continuous electrical pulses to branches of certain cranial nerves."

"Bridge is a small electrical nerve stimulator device that contains a battery-powered chip and wires that are applied around a patient's ear. It requires a prescription and is offered to qualified healthcare professionals. The Bridge kit includes everything needed to apply the device."

"Bridge ("Device") is a battery-operated micro-stimulation appliance designed as a disposable product for a single use. The device is placed behind the patient's ear and connected to stimulation needles on the auricle. The Device offers regular therapy over several days. The Device transmits low-frequency electric pulses to exposed nerve endings."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170018.pdf

<https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-device-use-helping-reduce-symptoms-opioid-withdrawal>

<https://clinicaltrials.gov/study/NCT03555266>

<https://www.masimo.ca/siteassets/en-ca/documents/pdf/plm-14896a-product-information-bridge-hcp-canada3.pdf>

<https://www.masimo.ca/siteassets/en-ca/documents/pdf/lab-11540b3.pdf>

Manufacturer: Innovative Health Solutions, Inc., later acquired and marketed by Masimo.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170018.pdf

<https://www.mobihealthnews.com/news/masimo-announces-device-designed-reduce-opioid-withdrawal-symptoms>

Website: <https://www.masimo.ca/products/Therapy/bridge/>

Primary Indications: Indicated for use to reduce the symptoms of opioid withdrawal in patients 18 years of age or older.

"The NSS-2 Bridge is indicated for use to reduce the symptoms of opioid withdrawal."

"The indication for the NSS-2 BRIDGE is for the treatment of clinical symptoms related to opioid consumption and opioid withdrawal. These symptoms include abdominal pain, anxiety and post-operative nausea and vomiting"

"Bridge™ is a percutaneous nerve field stimulator (PNFS) system, that can be used as an aid to reduce

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the symptoms of opioid withdrawal, through application to branches of Cranial Nerves, V, VII, IX, and X, and the occipital nerves identified by transillumination.”

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?ID=DEN170018>

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170018.pdf

<https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-device-use-helping-reduce-symptoms-opioid-withdrawal>

<https://clinicaltrials.gov/study/NCT03555266>

<https://www.masimo.ca/siteassets/en-ca/documents/pdf/lab-11540b3.pdf>

Is it FDA Approved?: Yes, FDA-granted marketing authorization (De Novo pathway as Class II device).

"The U.S. Food and Drug Administration today granted a new indication to an electric stimulation device for use in helping to reduce the symptoms of opioid withdrawal."

Sources:

<https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-device-use-helping-reduce-symptoms-opioid-withdrawal>

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170018.pdf

FDA Approval Details: Granted marketing authorization via the De Novo premarket review pathway (for novel low- to moderate-risk devices, creating a new Class II classification). De Novo decision date: November 15, 2017. De Novo number: DEN170018. New regulation: 21 CFR 882.5896; Product code: PZR (Percutaneous nerve stimulator for substance use disorders). Masimo Bridge maintains the same clearances post-acquisition.

"The FDA reviewed the NSS-2 Bridge device through the de novo premarket review pathway, a regulatory pathway for low- to moderate-risk devices of a new type."

Sources:

<https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-device-use-helping-reduce-symptoms-opioid-withdrawal>

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?ID=DEN170018>

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170018.pdf

<https://www.federalregister.gov/documents/2018/02/05/2018-02202/medical-devices-neurological-devices-classification-of-the-percutaneous-nerve-stimulator-for>

How It Works: The battery-powered device is placed behind the ear and connected to three needle arrays that deliver continuous electrical pulses to auricular branches of cranial nerves V, VII, IX, and X, modulating brain activity to reduce opioid withdrawal symptoms.

"The NSS-2 Bridge is a small, battery-powered, percutaneous electrical nerve field stimulator (PENFS) that adheres to the skin behind the patient's ear and delivers continuous electrical pulses to branches of certain cranial nerves."

"The NSS-2 BRIDGE is a percutaneous nerve field stimulator (PNFS) system, that can be used as an aid to reduce the symptoms of opioid withdrawal, through application to branches of Cranial Nerves V, VII, IX and X, and the occipital nerves identified by transillumination". "According to their manufacturers, these devices work by sending mild electrical pulses to certain nerves in and around the ear. These pulses send a message to the brain to fill empty receptors with endorphins – the same kind of endorphins people get when running."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170018.pdf

<https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-device-use-helping-reduce-symptoms-opioid-withdrawal>

https://www.accessdata.fda.gov/cdrh_docs/pdf20/K201873.pdf

<https://drugfree.org/article/earpiece-relieves-opioid-withdrawal/>

Frequency Used: Alternating current at 1–10 kHz with variable pulse widths.

"The device delivers alternating current at frequencies of 1-10 kHz with variable pulse widths."

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"The BRIDGE device settings are standardized and deliver 3.2 volts with alternating frequencies (1 ms pulses of 1 Hz and 10 Hz) every 2 s."

"The stimulator uses an integrated 3-volt battery, has a load impedance range of 1 k to 10 k Ω with 3.2 volt maximum, and symmetrical, biphasic stimulation cycles occur at a frequency of 0.125 Hz with periodic rest."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170018.pdf

<https://pmc.ncbi.nlm.nih.gov/articles/PMC9323550/>

<https://ichgcp.net/clinical-trials-registry/NCT04514627>

Is it Non-Thermal?:

Yes. The device functions purely as a percutaneous nerve stimulator, using strictly electrical pulses to induce neuromodulation and the release of endogenous opioids, completely avoiding the generation or transfer of thermal heat energy to the patient.

Sources:

<https://pmc.ncbi.nlm.nih.gov/articles/PMC9323550/>

Is it Non-Ionizing?: Yes. As a battery-operated nerve field stimulator, it utilizes non-ionizing electrical impulses delivered directly through tiny percutaneous needles, carrying zero risk of the cellular-level damage associated with ionizing radiation like X-rays.

Sources:

<https://clinicaltrials.gov/study/NCT03555266>

Side Effects: Generally well-tolerated with no serious device-related adverse events reported in clinical studies or post-market data. Common: mild ear discomfort (e.g., pain, tingling, itching at needle sites; 18.4% of patients). Less common: dizziness, nausea, or skin irritation. These are transient and resolve after removal. Contraindications include hemophilia, psoriasis vulgaris, or pregnancy.

"The most common adverse event was discomfort due to application of the device (e.g., pain, tingling, itching or burning sensation at the stimulation site)."

"No serious adverse events were reported."

Clinical studies report it generally "lacks systemic side effects," however, patients may experience some "mild discomfort when first placed" or "localized cutaneous irritation" where the percutaneous needles puncture the skin. Because it uses needles and electrical stimulation, the FDA warns that "The device is contraindicated for patients with hemophilia, patients with cardiac pacemakers or those diagnosed with psoriasis vulgaris."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN170018.pdf

<https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-device-use-helping-reduce-symptoms-opioid-withdrawal>

<https://pmc.ncbi.nlm.nih.gov/articles/PMC9323550/>

3. IB-Stim is a prescription-only, non-invasive percutaneous nerve field stimulator (PNFS) device that delivers electrical pulses via needle arrays placed behind the ear to stimulate auricular branches of cranial nerves for reducing functional abdominal pain associated with irritable bowel syndrome (IBS) in pediatric patients.

"The IB-Stim is a percutaneous electrical nerve field stimulator (PENFS) system intended to be used in patients 11-18 years of age with functional abdominal pain associated with irritable bowel syndrome (IBS)."

"The IB-Stim is a battery-powered, percutaneous electrical nerve field stimulator (PENFS) that adheres to the skin behind the patient's ear and delivers continuous electrical pulses to branches of certain cranial nerves."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf

<https://ibstim.com/>

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Manufacturer: NeurAxis, Inc. (The device was initially developed under the company name Innovative Health Solutions).

“The IB-Stim device invented and distributed by NeurAxis, Inc. ...”

Sources:

<https://ir.neuraxis.com/news-releases/news-release-details/neuraxis-receives-new-fda-510k-clearance-ib-stim-expanding-its>

<https://ibstim.com/faq-items/does-the-ib-stim-device-work-for-everyone/>

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf

Website: <https://ibstim.com/>

<https://neuraxis.com/ib-stim/>

<https://neuraxis.com/ib-stim-for-adults/>

Primary Indications: "The IB-Stim is a percutaneous electrical nerve field stimulator (PENFS) system intended to be used in patients 8 years and older with functional abdominal pain associated with irritable bowel syndrome (IBS) and functional dyspepsia (FD)."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/pdf25/K252024.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?ID=DEN180057>

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf

<https://ir.neuraxis.com/news-releases/news-release-details/neuraxis-awarded-first-ever-fda-clearance-treatment-pediatric>

Is it FDA Approved?: Yes.

"Introducing IB-Stim®, the first FDA cleared, drug-free method for treating functional abdominal pain associated with IBS and functional dyspepsia in patients age 8 and older."

Sources:

<https://ibstim.com/>

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf

FDA Approval Details:

The De Novo Foundation (Generation 1)

Because it was a first-of-its-kind non-pharmacological device intended to treat functional abdominal pain associated with Irritable Bowel Syndrome (IBS) in pediatric patients, there was no legally marketed predicate device available for a standard comparison. Therefore, the FDA initially authorized the IB-Stim through the rigorous De Novo classification pathway.

- De Novo Request Number: DEN180057
- Decision Date: June 7, 2019
- Original Indication: The foundational clearance authorized the prescription-only device to aid in the reduction of functional abdominal pain in adolescents aged 11 to 18 years old with IBS. The original protocol called for using one device for 120 hours (5 days) a week for up to 3 consecutive weeks.

Recent 510(k) Label Expansions

Following the foundational De Novo authorization, NeurAxis successfully utilized the standard 510(k) premarket notification pathway to drastically expand the addressable market and clinical indications for the IB-Stim platform:

- Age Range and Protocol Expansion (K241533): Cleared on October 30, 2024, this critical update expanded the authorized patient age range from 11–18 years old down to 8–21 years old. It also updated the treatment protocol to allow the use of 1 device per week for up to 4 consecutive weeks.
- Functional Dyspepsia Expansion (K250451): Cleared on May 15, 2025, the FDA expanded the device's label beyond just IBS. It became the first-ever device cleared for the treatment of functional dyspepsia (FD) and its associated nausea symptoms in patients aged 8 to 21 years old.

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- **Broad Age Expansion (K252024):** Cleared on October 16, 2025, the FDA further expanded the marketing authorization for the device, removing the upper age cap entirely and allowing it to be used in patients 8 years and older for both IBS and FD.

Sources:

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?ID=DEN180057>

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K241533>

https://www.accessdata.fda.gov/cdrh_docs/pdf24/K241533.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K250451>

https://www.accessdata.fda.gov/cdrh_docs/pdf25/K250451.pdf

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K252024>

https://www.accessdata.fda.gov/cdrh_docs/pdf25/K252024.pdf

How It Works: The battery-powered device is placed behind the ear and connected to three needle arrays that deliver continuous electrical pulses to auricular branches of cranial nerves V, VII, IX, and X, modulating brain activity to reduce IBS-associated abdominal pain; worn for up to 5 days.

"The IB-Stim is a small, battery-powered, percutaneous electrical nerve field stimulator (PENFS) that adheres to the skin behind the patient's ear and delivers continuous electrical pulses to branches of certain cranial nerves."

"The IB-Stim is a device that delivers electrical stimulation through percutaneous electrodes to areas usually innervated by branches of occipital nerves and cranial nerves V, VII, IX and X". "This stimulation targets central pain pathways... to reduce abdominal pain in patients with IBS." Clinicians use a transillumination light to locate the proper placement for the tiny needles on the patient's ear, ensuring the current safely reaches the targeted cranial nerve bundles.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf

<https://clinicaltrials.gov/study/NCT04428619>

Frequency Used: "The device settings are standardized and deliver 3.2 volts with alternating frequencies (1 ms pulses of 1 Hz and 10 Hz) every 2 s."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf

<https://clinicaltrials.gov/study/NCT04428619>

Is it Non-Thermal?: Yes. The technology utilizes a "battery-operated micro-stimulation appliance" to deliver ultra-low-frequency electric pulses. It relies entirely on electrical neuromodulation of the central pain pathways and avoids the generation or transfer of thermal heat energy to the patient's skin or ear cartilage.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf

https://www.accessdata.fda.gov/cdrh_docs/pdf24/K241533.pdf

Is it Non-Ionizing?: Yes. As a percutaneous electrical nerve field stimulator, the IB-Stim uses basic, non-ionizing electrical impulses delivered via small percutaneous needles, presenting none of the cellular-level risks associated with ionizing radiation exposure.

Sources:

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf

<https://ibstim.com/fda-classification/>

Side Effects: Generally well-tolerated with no serious device-related adverse events reported in clinical studies or post-market data. Common: mild ear discomfort (e.g., pain, tingling, itching at needle sites; 18.4% of patients). Less common: dizziness, nausea, or skin irritation. These are transient and resolve after removal. Contraindications include hemophilia, psoriasis vulgaris, or pregnancy.

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"The most common adverse event was discomfort due to application of the device (e.g., pain, tingling, itching or burning sensation at the stimulation site)."

"No serious adverse events were reported."

The therapy is generally well-tolerated, though clinical trials noted that because the application involves tiny needles, "one patient in the placebo group had a fainting episode due to fear of needles." The most common device-related adverse events involve localized issues at the ear, including a "2.8% Incidence of Dermatitis at lead implantation site or Generator placement site" and rare occurrences of minor bleeding. The FDA warns that "The device is contraindicated for use by patients with cardiac pacemakers, hemophilia, and psoriasis vulgaris."

Sources:

https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN180057.pdf

<https://pmc.ncbi.nlm.nih.gov/articles/PMC10142928/>

<https://ibstim.com/safety-profile/>