Quell
Fibromyalgia

Quell® Fibromyalgia Prescribing Information

FDA De Novo authorization 2022

Indications

Quell Fibromyalgia is a transcutaneous electrical nerve stimulation (TENS) device indicated as an aid for reducing the symptoms of fibromyalgia in adults with high pain sensitivity. The device may be used during sleep. The device is labeled for use only with compatible NeuroMetrix electrodes.

Limitations

The sale, distribution, and use of Quell Fibromyalgia are restricted to prescription use in accordance with 21 CFR 801.109. Many participants in the clinical study were also taking medication for fibromyalgia and it was difficult to assess the effects of the device compared to medication.

Dosage

Daily use of the device should not exceed 8-hours of stimulation and 15-hours of wear. The safety and effectiveness of the device when used for more than 8 therapy hours per day is not well characterized.

Contraindications

- The device is contraindicated for use by patients who have a cardiac pacemaker, implanted defibrillator, other implanted electronic device, or implanted metal near the device, because this may cause electric shock, burns, electrical interference, or death.
- The stimulation electrodes should not be placed across or through the head, directly on the eyes, covering the mouth, on the front of the neck, on the chest or upper back, or crossing the heart.
- The device cannot be used while driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.

Precautions

- Fibromyalgia is believed to be, at least partially, a central nervous system condition resulting from central sensitization and deficient descending pain inhibition. TENS has not been demonstrated to be effective for other pain conditions of central origin, including headache.
- If patient experiences uncomfortable stimulation and cannot control the device via their mobile app then they should stop stimulation immediately by double-tapping the enclosure and remove the device.
- Patient may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- Patient should use caution if stimulation is applied over areas of skin that lack normal sensation.
- Patient should use this device only with electrodes and accessories recommended by the manufacturer.
- TENS is not a substitute for pain medications and other pain management therapies.
- TENS devices have no curative value.
- TENS is a symptomatic treatment and, as such, may suppress the sensation of pain that would otherwise serve as a protective mechanism.
- The long-term effects of electrical stimulation are unknown.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- The safety of electrical stimulation during pregnancy has not been established.
- A patient with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
- A patient with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.

- The device is MR unsafe and should not be used in a magnetic resonance imaging environment. The device presents a projectile hazard.

Warnings

- Do not place the stimulation electrodes across or through the head, directly on the eyes, covering the mouth, on the front of the neck, on the chest or upper back, or crossing the heart.
- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- Do not apply stimulation when in the bath or shower.
- Apply stimulation only to normal, intact, clean, healthy skin.
- No modification of this device is allowed.
- Simultaneous connection of a patient to high frequency surgical equipment may result in burns at the site of the stimulator electrodes and possible damage to the stimulator.
- Operation in close proximity (e.g., 1 meter) to shortwave or microwave therapy medical equipment may produce instability in the stimulator output.
- Application of electrodes near the thorax may increase the risk of cardiac fibrillation.
- Do not remove the device from the leg before therapy has stopped. Check that the light is not illuminated on device, otherwise patient may experience an uncomfortable sensation when they remove the device.
- Do not use the device if it has been accidentally damaged, causing the housing to come open, or an unexpected shock may result.
- Do not apply stimulation over the neck because this could cause severe muscle spasms resulting in airway closure, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across the chest, because the introduction of electrical current into the chest may cause heart rhythm disturbances, which could be lethal.
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- Use caution if patient has a tendency to bleed internally, such as following an injury or fracture.
- Consult with a physician prior to using the device after a recent surgical procedure, because stimulation may disrupt the healing process.
- Do not use the device on children under the age of 18.
- Keep this device out of the reach of children.

Adverse Reactions

- Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.
- Patients should stop using the device and should consult with a physician if they experience adverse reactions from the device.