

Warnings and Precautions

gammaCore™ (non-invasive vagus nerve stimulator)

Warnings

- Safety and efficacy of gammaCore have not been evaluated in the following patients:
 - Patients diagnosed with narrowing of the arteries (carotid atherosclerosis)
 - Patients with metallic device such as a stent, bone plate, or bone screw implanted at or near their neck
 - Patients who have had surgery to cut the vagus nerve in the neck (cervical vagotomy)
 - Pediatric patients (younger than 12 years of age)
 - Pregnant women
 - Patients with uncontrolled hypertension, hypotension, bradycardia, or tachycardia

Precautions

- The long-term safety and effectiveness of the gammaCore device has not been demonstrated in adolescents 12-17 years of age. Due to hormonal and cognitive development changes in adolescents, this population should be closely monitored while using the device. The use of the device in this population is based on extrapolated data from a clinical study in adults.
- You must read the *Instructions for Use* before using gammaCore.
- Only use gammaCore as described in these *Instructions for Use* or as otherwise directed by your health care provider.
- Only use an electroCore-approved electrode spray and gel with gammaCore.

Note: This list is not all inclusive. Please refer to the gammaCore *Instructions for Use* for all of the important contraindications, warnings, and precautions before using or prescribing this product.

Important Safety Information

gammaCore™ (non-invasive vagus nerve stimulator)



Refer to instruction
manual



Information or additional
information available



Follow operating
instructions

gammaCore™ (non-invasive vagus nerve stimulator) is intended to provide non-invasive vagus nerve stimulation (nVNS) on the side of the neck. gammaCore is indicated for:

- The preventive treatment of migraine headache in adolescent (age 12 and older) and adult patients.
- The acute treatment of pain associated with migraine headache in adolescent (age 12 and older) and adult patients.
- Adjunctive use for the preventive treatment of cluster headache in adult patients.
- The acute treatment of pain associated with episodic cluster headache in adult patients.
- Treatment of hemicrania continua and paroxysmal hemicrania in adults.

The safety and effectiveness of gammaCore has not been established in the acute treatment of chronic cluster headache.

The long-term effects of the chronic use of the device have not been evaluated.

Safety and efficacy of gammaCore has not been evaluated and therefore is NOT indicated for:

- Adolescent patients with congenital cardiac issues.
- gammaCore contraindications include but are not limited to:
 - Patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device.
 - Patients who are using another device at the same time (e.g., TENS Unit, muscle stimulator) or any portable electronic device (e.g., mobile phone).



Scan the QR code for
Important Safety Information
and Instructions for Use.