

Indication and Important Safety Information



gammaCore Sapphire™ (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 and acute treatment of cluster headache
- The preventive and acute treatment of migraine headache

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

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 with metallic device such as a stent, bone plate or bone screw implanted at or near their neck.
- 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)

Warnings

- Safety and efficacy of gammaCore have not been evaluated in the following patients:
 - Patients diagnosed with narrowing of the arteries (carotid atherosclerosis)
 - Patients who have had surgery to cut the vagus nerve in the neck (cervical vagotomy)
 - Pediatric patients (less than 12 years of age)
 - Pregnant women
 - Patients with clinically significant hypertension, hypotension, bradycardia, or tachycardia

Precautions

- You must read the gammaCore *Instructions for Use* before using gammaCore.
- Only use gammaCore as described in these *Instructions for Use* or as otherwise directed by your Healthcare Provider.
- Only use an electroCore-approved electrode 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.

Doctor or Healthcare Professional authorization required.