

US Indication and ISI

gammaCore® (non-invasive vagus nerve stimulator) is indicated for the acute treatment of pain associated with episodic cluster headache and migraine headache in adult patients

- The safety and effectiveness of gammaCore (nVNS) have not been established in the acute treatment of chronic cluster headache
- gammaCore has not been shown to be effective for the prophylactic treatment of migraine headache, chronic cluster headache, or episodic cluster headache
- The long-term effects of the chronic use of gammaCore have not been evaluated
- Safety and efficacy of gammaCore have not been evaluated in the following patients, and therefore it is NOT indicated for:
 - Patients with an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device
 - 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
 - Pregnant women
 - Patients with clinically significant hypertension, hypotension, bradycardia, or tachycardia
- Patients should not use gammaCore if they:
 - Have a metallic device such as a stent, bone plate, or bone screw implanted at or near their neck
 - Are using another device at the same time (e.g., TENS Unit, muscle stimulator) or any portable electronic device (e.g., mobile phone)

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