

FACT SHEET FOR PATIENTS

Emergency Use of gammaCore Sapphire CV During the COVID-19 Pandemic

July 10, 2020

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because your healthcare provider believes you may benefit from the gammaCore Sapphire CV. This device may be effective for use at home or in healthcare settings to treat your shortness of breath and the reduced air flow through your lungs due to worsening of your asthma because of known or suspected COVID-19 infection by using non-invasive vagus nerve stimulation (VNS) on either side of your neck, when approved drug therapies are not tolerated or do not provide sufficient symptom relief as determined by your healthcare provider.

This Fact Sheet contains information to help you understand the risks and benefits of using the gammaCore Sapphire CV during the COVID-19 pandemic. After reading this Fact Sheet, if you have questions or would like to discuss the information provided further, please talk to your healthcare provider.

For the most up to date information on COVID-19 please visit the CDC Coronavirus Disease 2019: (COVID-19) webpage:

<https://www.cdc.gov/COVID19>

What is COVID-19?

COVID-19 is a disease caused by the SARS-CoV-2 virus. This new coronavirus was first found in people in December 2019. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat, or new loss of taste or smell. Early reports of COVID-19 infections demonstrate a high level of aggressive, prolonged inflammation in the airways which may result in significant worsening of asthma symptoms in the large asthmatic population.

What do I need to know about the emergency use of the gammaCore Sapphire CV?

The use of gammaCore Sapphire CV has not been evaluated in any patients with COVID-19.

The emergency use of the gammaCore Sapphire CV has been authorized under an Emergency Use Authorization for acute use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider, by using non-invasive vagus nerve stimulation (nVNS) on either side of the neck, during the Coronavirus Disease 2019 (COVID-19) pandemic. A healthcare provider may choose to prescribe the gammaCore Sapphire CV to you.

You have the option to refuse this product. If you choose to decline use of this device, you should discuss any alternative options or questions/concerns with your health care provider.

What is gammaCore Sapphire CV?

The gammaCore Sapphire CV is a handheld, rechargeable, portable device designed to stimulate the vagus nerve on either side of your neck in a non-invasive manner in order to attempt to improve the airflow to your lungs and attempt to improve your shortness of breath due to the worsening of your asthma because of known or suspected COVID-19 infection.

You will be trained by your HCP on how to use this device. In general, the user applies the gammaCore Sapphire CV over the vagus nerve by holding the stimulation surfaces against the skin of the neck to the side of the trachea (windpipe). The device may be operated by a healthcare provider or by the patient (self-treatment).

How can I learn more? The most up-to-date information on COVID-19 is available at the CDC General Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.

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What should I know about using gammaCore Sapphire CV?

The gammaCore Sapphire CV is not for use:

- If you have an active implantable medical device, such as a pacemaker, hearing aid implant, or any implanted electronic device.
- If you have a metallic device, such as a stent, bone plate, or bone screw, implanted at or near your neck. You must inform your HCP of any planned surgeries that may involve implants.
- If you have an open wound, rash, infection, swelling, cut, sore, drug patch, or surgical scar(s) on your neck at the treatment location

In addition, you should not use the gammaCore Sapphire CV:

- While driving, operating machinery, or during any activity that may put you at risk of injury;
- In an explosive atmosphere or in the presence of flammable gas mixtures;
- If you have wet skin, are in water, or just stepped out of the water (e.g. shower, bath, pool); or
- If you are using another device at the same time (e.g. TENS Unit, muscle stimulator) or any portable electronic device.

Do not use the gammaCore Sapphire CV near the following items, which can affect the performance of the gammaCore Sapphire CV:

- Microwave machines, magnetic resonance imaging, radio frequency surgical, or computer-aided tomography machines; or
- Wireless communications equipment, such as:
 - wireless home network devices,
 - mobile phones,
 - walkie-talkies,
 - cordless telephones and their base stations

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Keep the gammaCore Sapphire CV at least 3.3 m (10.8 feet) away from these items while in use.

What is an EUA?

The United States FDA has made certain devices available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Services' (HHS's) declaration that circumstances exist to justify the emergency use of devices during the COVID-19 pandemic.

The gammaCore Sapphire CV has been made available under an EUA, and has not undergone the same type of review as an FDA-approved or cleared device. FDA may issue an EUA when certain criteria are met, including when there are no adequate, approved available alternatives, and when based on the totality of scientific evidence available, it is reasonable to believe that this device meets certain criteria for safety, performance, and labeling, and may be effective at treating COVID-19.

The EUA for gammaCore Sapphire CV is in effect for the duration of the COVID-19 declaration justifying emergency use of this device, unless terminated or revoked (after which the product may no longer be used).

What are the known and potential benefits and risks of gammaCore Sapphire CV?

Known and potential benefits include:

- Improved airflow through your lungs
- Improvement in symptoms of shortness of breath

Known and potential risks include:

- Discomfort at the site of treatment
- Irritation/redness of the skin at the site of treatment
- Pain of the face, head, and/or neck area (including toothache)
- Muscle twitching of the face, head, and/or neck area (including facial droop and lip pull)
- Headache/migraine
- Dizziness

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- Tingling, prickling, or a feeling of “pins and needles” on the skin where the device is applied

What are the alternatives to gammaCore Sapphire CV known and the potential benefits and risks of such products?

COVID-19 could potentially worsen your symptoms of asthma. While there are approved medicines, there are no FDA approved or cleared devices to treat your acute shortness of breath and the reduced air flow through your lungs. Approved medicines to manage your asthma as a patient affected by COVID-19 include rescue inhaler medications (bronchodilators).

Benefits of these medications include:

- Proven safety and effectiveness in managing symptoms of your asthma
- Your health care provider may be familiar with their use, dosing, side effects

Risks of these medications include:

- Rapid heart rate
- Tremors
- Headache
- Mood changes
- Weight gain
- Thrush (fungal infection of your throat)
- Cough
- Sore Throat

Is gammaCore Sapphire CV FDA-approved or cleared?

No. The gammaCore Sapphire CV is not approved or cleared by the United States (U.S.) FDA for acute use at home or in a healthcare setting to treat adult patients with known or suspected COVID-19 who are experiencing exacerbation of asthma-related dyspnea and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by their healthcare provider by using non-invasive vagus nerve stimulation (VNS) on either side of the patient’s neck. An FDA approved or cleared device should be used, when applicable and available.

How can I learn more? The most up-to-date information on COVID-19 is available at the CDC General Webpage: <https://www.cdc.gov/COVID19>. In addition, please also contact your healthcare provider with any questions/concerns.