

FACT SHEET FOR PATIENTS

Emergency Use of the InSee Incentive Spirometer Accessory

June 30, 2021

Coronavirus
Disease 2019
(COVID-19)

You are being given this Fact Sheet because your healthcare provider used the InSee device as an accessory to your use of the Vyair Medical AirLife incentive spirometer. The InSee device tracks your use of the Vyair Medical AirLife incentive spirometer as an aid in treatment of respiratory conditions associated with COVID-19.

This Fact Sheet contains information to help you understand the risks and benefits of using the InSee device for the treatment of respiratory conditions associated with COVID-19. 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 COVID19, please visit the CDC Coronavirus Disease 2019 (COVID-19) webpage:

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

What is the COVID-19?

COVID-19 is caused by the SARS-CoV-2 virus. The virus can cause mild to severe respiratory illness and has spread globally, including the United States. 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.

What is the InSee device?

The InSee device is designed to quantitatively track patient usage of the Vyair Medical's AirLife incentive spirometer to aid in the treatment of respiratory conditions by patients with COVID-19 in hospital settings. The InSee is not intended for use by patients with recent eye surgery, a pneumothorax (collapsed lung), or an aneurysm in their brain, chest, or abdomen.

Why will the InSee device be this used on me?

The InSee device is an incentive spirometer accessory for the Vyair Medical AirLife incentive spirometer that has to potential to aid in the treatment of patient respiratory conditions associated with COVID-19 while in a hospital setting.

What are the known and potential risks and benefits of the InSee device?

Known and potential risks of using the **InSee** include:

- Improper attachment – HCP should be instructed on proper attachment techniques so that you can use the spirometer and InSee successfully. The InSee Device User Manual shows how the InSee should be attached to the spirometer to ensure proper readings can be measured
- Calibration values and incorrect reads – Prior to use of the InSee device, it is carefully calibrated as part of quality control. If you notice improper readings, let your healthcare provider know, because the InSee may need to be recalibrated; overall, an incorrect reading should not affect your treatment, as incentive spirometers are used as preventative tools and not diagnostic tools
- Display malfunction – Inaccurate monitoring of patient usage of incentive spirometer and InSee can potentially lead to inaccurate assessment of your respiratory condition

Known and potential benefits of using the **InSee** include:

- Provides an accurate record of your incentive spirometer usage
- May improve clinical monitoring of your condition
- Encourages you to participate in your recovery
- Helps to reduce healthcare provider burden and exposure to patients with COVID-19

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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Is the InSee device FDA-approved or cleared?

No. The **InSee** is not FDA-approved or cleared. The FDA has authorized this use of the **InSee** through an emergency access mechanism called an Emergency Use Authorization (EUA).

What is an EUA?

The United States FDA has made the **InSee** available under an emergency access mechanism called an EUA. The EUA is supported by the Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of medical devices during the COVID-19 pandemic.

The **InSee** under this EUA 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, which includes that there are no adequate, approved, available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the **InSee** device meets certain criteria for safety, performance, and labeling, and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the **InSee** device to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for the **InSee** is in effect for the duration of the COVID-19 declaration justifying emergency use of this device, unless terminated or revoked (after which the device may no longer be used

You have the option to refuse this device. However, your doctor may be recommending this device because an FDA-cleared device may not be available due to shortages caused by COVID-19. If you choose to decline use of this device, you should discuss any alternative options with your healthcare provider.

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