

FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of the TransAeris® Diaphragm Pacing System During the COVID-19 Pandemic
April 13, 2020

Coronavirus
Disease 2019
(COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the TransAeris® Diaphragm Pacing System during the COVID-19 pandemic.

Manual, including cleaning instructions, patient monitoring recommendations, and other labeling information for the TransAeris® Diaphragm Pacing System.

All patients who are treated with the TransAeris® Diaphragm Pacing System will receive the Fact Sheet for Patients: Emergency Use of the TransAeris® Diaphragm Pacing System During the COVID-19 Pandemic

What are the symptoms of COVID-19?

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days, but may range 2-14 days.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States, which may pose risks for public health. Please check the CDC webpage for the most up to date information.

What do I need to know about the emergency use of Diaphragmatic Pacing Stimulator Systems?

- Devices that meet certain criteria for safety, performance, and labeling have been authorized for emergency use.
- The TransAeris® Diaphragm Pacing System is authorized for use in healthcare settings to assist in weaning patients determined by their healthcare provider to be at high risk of weaning failure off ventilators, for no more than 30 days.
- Healthcare providers should review the Surgical Procedures for Implantation of TransLoc Electrodes for TransAeris® System, TransAeris® System User

Use appropriate personal protective equipment when caring for individuals suspected of having COVID-19 as outlined in the CDC *Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings* or on the CDC webpage on *Infection Control*. Current information on COVID-19 for healthcare providers is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

Who should be receiving this medical device?

Patients with COVID-19 and other illnesses or conditions that require mechanical ventilation, are not spontaneously breathing, and are expected to require prolonged ventilation.

What are the known and potential benefits and risks of the TransAeris® Diaphragm Pacing System?

Potential benefits of the TransAeris® Diaphragm Pacing System:

- Maintenance of diaphragm muscle strength to promote early weaning from mechanical ventilation
- Avoidance of risks of prolonged mechanical ventilation such as ventilator associated pneumonia (VAP), ventilator associated lung injury (VALI), muscle wasting, laryngotracheal injury, and death

Potential risks of the TransAeris® Diaphragm Pacing System:

- Infection, electrode lead breakage and migration, heart rhythm disturbance, pneumothorax, bleeding, implant procedure-related death
- Reduced familiarity of healthcare providers with the TransAeris® Diaphragm Pacing System
- Lack of effectiveness, despite use as intended

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500 (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) or by calling **1-800-FDA-1088**

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What are the alternatives to the TransAeris® Diaphragm Pacing System and the known and potential benefits and risk of such products?

Alternatives to the TransAeris® Diaphragm Pacing System that is authorized under this Emergency Use Authorization (EUA) include “traditional” weaning strategies based on manipulation of ventilator settings modes which allow or encourage gradually increased patient effort and stamina for breathing.

Benefits associated with “traditional” weaning strategies:

- Non-invasive
- Healthcare provider familiarity with standard ventilator weaning strategies, including those described in clinical guidelines

Risks associated with “traditional” weaning strategies:

- Prolonged mechanical ventilation with associated risk, such as ventilator associated pneumonia (VAP), ventilator associated lung injury (VALI), muscle wasting, laryngotracheal injury, and death

What is an EUA?

The United States (U.S.) FDA has made the TransAeris® Diaphragm Pacing System available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by a Secretary of Health and Human Service’s (HHS’s) declaration that circumstances exist to justify the emergency use of medical devices, including alternative devices used as medical devices, due to shortages during the COVID-19 pandemic.

The TransAeris® Diaphragm Pacing System made available under an EUA has not undergone the full validation of an FDA-approved or cleared device. However, in the absence of an FDA-approved or cleared alternative and based on the totality of scientific evidence, it is reasonable to believe that the TransAeris® Diaphragm Pacing System may be effective in assisting weaning of patients off ventilators and, as a result, may increase the availability of ventilators for other patients. The EUA for these devices are in effect for the duration of the COVID-19 pandemic, unless terminated or revoked (after which the device may no longer be used).

An FDA approved or cleared device should be used instead of the TransAeris® Diaphragm Pacing System under EUA, when applicable and available.

Where can I go for updates and more information?

CDC webpages:

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

Healthcare Professionals:

<https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html>

Infection Prevention and Control Recommendations in Healthcare Settings:

<https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html>

Infection Control: <https://www.cdc.gov/coronavirus/2019-ncov/infection-control/index.html>

FDA webpages:

General: www.fda.gov/novelcoronavirus

EUAs: (includes links to patient fact sheet and

manufacturer’s instructions) <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>

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