

FACT SHEET FOR HEALTHCARE PROVIDERS

Coronavirus
Disease 2019
(COVID-19)

Emergency Use of the B. Braun Space and Outlook Pumps During the COVID-19 Pandemic

April 11, 2020

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, and Outlook ES (hereafter “B. Braun Space and Outlook Pumps”).

The B. Braun Space and Outlook Pumps are authorized for emergency use for the tracheal delivery of continuous nebulized medications into a nebulizer to treat patients with or suspected of having the Coronavirus Disease 2019 (COVID-19), decreasing the exposure of healthcare workers to such patients during the COVID-19 pandemic. The Infusomat Space Volumetric Infusion Pump System is authorized to be used in ground medical transport situations.

All patients who are treated with the B. Braun Space and Outlook Pumps during the COVID-19 pandemic will receive the Fact Sheet for Patients: Emergency Use of the B. Braun Space and Outlook Pumps 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 B. Braun Space and Outlook Pumps?

The B. Braun Space and Outlook Pumps have received FDA premarket clearance for use in the continuous infusion of medications, nutrition, and/or other fluids. The additional emergency use authorization is for the use in the tracheal delivery of continuous nebulized medications into a nebulizer. The Infusomat Space Volumetric Infusion Pump System has also been authorized for the use in ground medical transport.

The device should be used according to the manufacturer’s instructions for use provided with the device and the recommendations in this Healthcare Provider Fact Sheet, alongside the hospital’s protocol for integrating the pumps with a nebulizer.

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 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).

What are the known and potential benefits and risks of the B. Braun Space and Outlook Pumps?

Potential benefits of the B. Braun Space and Outlook Pumps for use in the tracheal delivery of continuous nebulized medications into a nebulizer include:

- Prolonged treatment with nebulized medications
- Controlled rate flow of medication into the nebulizer.
- Decreased exposure between healthcare providers and affected patients or those suspected of having COVID-19.

Potential risks of the B. Braun Space and Outlook Pumps for use in the tracheal delivery of continuous nebulized medications into a nebulizer include:

- Risks to patients are over- or under-delivery of medication.

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 is an EUA?

The United States FDA has authorized the emergency use of the B. Braun Space and Outlook Pumps for the tracheal delivery of continuous nebulized medications into a nebulizer to treat affected patients or those suspected of having the COVID-19 and to decrease the exposure of healthcare providers to such patients during the COVID-19 pandemic under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the 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 use of the B. Braun Space and Outlook Pumps for the tracheal delivery of continuous nebulized medications into a nebulizer, and the addition of the ground medical transport environment for the Infusomat Space Volumetric Infusion Pump System, have 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, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that the B. Braun Space and Outlook Pumps may be effective for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat affected patients or those suspected of having the COVID-19 and to decrease the exposure of healthcare workers to such patients during the COVID-19 pandemic.

The EUA for the B. Braun Space and Outlook Pumps is in effect for the duration of the COVID-19 declaration justifying emergency use of these devices, unless terminated or revoked (after which the products may no longer be used for the emergency use).

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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