

April 13, 2020

Dear Valued Customer:

Due to the COVID-19 public health emergency B. Braun Medical Inc. received FDA authorization for Emergency Use of the **B. Braun Outlook® ES, B. Braun Infusomat® Space Volumetric Infusion Pump System and the B. Braun Perfusor® Space Syringe Infusion Pump System** for tracheal delivery of continuous nebulized medications into a nebulizer to treat patients of all ages with or suspected of having COVID-19 and to decrease the exposure of healthcare providers (HCP) to such patients during the COVID-19 pandemic. In addition, the Infusomat Space pump may be used in ground medical transport situations during the COVID-19 pandemic. Attached you will find a copy of the temporary label and instructions for use for this new temporary indication.

**What you need to know:**

- The B. Braun Outlook, Infusomat Space and Perfusor Space pumps have not been FDA cleared or approved for this emergency use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat patients with or suspected of having COVID-19 and for ground medical transport use of the Infusomat Space Volumetric Infusion Pump System
- The B. Braun Outlook, Infusomat Space and Perfusor Space pumps for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat patients of all ages with or suspected of having COVID-19 and for ground medical transport use of the Infusomat Space Volumetric Infusion Pump System are authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of the B. Braun Space and Outlook Pumps under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner
- Attached you will find the Fact Sheet for Healthcare Providers and the Fact Sheet for Patients. You must provide a copy of the B. Braun Pump Fact Sheet for Patients to any patient in whom you intend to use the pump for delivery of continuous nebulization of medication into a nebulizer.
- You must notify B. Braun if your institution intends to use the B. Braun Space and Outlook Pumps for this temporary emergency use indication by contacting B. Braun Medical Affairs at number or email below.
- In case of an adverse event, please contact immediately Medical Affairs to report the incident.

If you have any questions please contact B. Braun Medical Affairs at 1-800-854-6851 or [medInfo.us@bbraunusa.com](mailto:medInfo.us@bbraunusa.com) or visit our website [bbraunusa.com/en/company/newsroom/covid19](https://www.bbraunusa.com/en/company/newsroom/covid19)

Thank you for your continued partnership.

Stay healthy!

Attachments: Fact Sheet-HCP, Fact Sheet-Patient, Temporary Label

## **Coronavirus disease (COVID-19) Public Health Emergency**

**Labeling applicable for:**

**B. Braun Perfusor® Space Syringe Infusion Pump System**  
**B. Braun Infusomat® Space Volumetric Infusion Pump System**  
**B. Braun Outlook® ES**

### **New Additional Indications for Use**

The **Perfusor® Space Syringe Infusion Pump System** is also intended for tracheal delivery of continuous nebulized medications into a nebulizer to treat patients who have symptoms of or are suspected of having COVID-19 and to decrease the exposure of healthcare workers to such patients during the COVID-19 pandemic.

The **Infusomat® Space Volumetric Infusion Pump System** is also intended for tracheal delivery of continuous nebulized medications into a nebulizer to treat patients who have symptoms of or are suspected of having COVID-19 and to decrease the exposure of healthcare workers to such patients during the COVID-19 pandemic. It may be used in ground medical transport situations.

The **Outlook® ES** is also intended for tracheal delivery of continuous nebulized medications into a nebulizer to treat patients who have symptoms of or are suspected of having COVID-19 and to decrease the exposure of healthcare workers to such patients during the COVID-19 pandemic.

### **Instructions for Use**

There is no change to the instructions for use for the infusion pump or nebulizer. Reference applicable instructions provided with these devices.

*The New Additional Indications for Use have not been cleared by the FDA through the Premarket Notification Process and are only for use during the Coronavirus Disease (COVID-19) Public Health Emergency.*

# 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 13, 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.

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**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**

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### **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.

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**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**

# 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 13, 2020

## 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](http://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>

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

# FACT SHEET FOR PATIENTS

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

April 13, 2020

## Coronavirus Disease 2019 (COVID-19)

You are being given this Fact Sheet because your healthcare provider believes it is necessary to treat you with the Perfusor Space Syringe Infusion Pump System, Infusomat Space Volumetric Infusion Pump System, or Outlook ES (hereafter “B. Braun Space and Outlook Pumps”).

This Fact Sheet contains information to help you understand the benefits and risks of the B. Braun Space and Outlook Pumps for use in the tracheal delivery of continuous nebulized medications into a nebulizer. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

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- **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>
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### What is COVID-19?

COVID-19 is a disease caused by the SARS-CoV-2 virus. The virus, which can cause mild to severe respiratory illness, was first identified in Wuhan, China, and has now spread globally, including the United States. There is limited information available about the different types of illness that one may show if infected with the virus. The virus most likely spreads from one person to another at the time when a person shows signs or symptoms of being sick (e.g., fever, coughing, difficulty breathing, etc.).

### What do I need to know about the B. Braun Space and Outlook Pumps?

A healthcare provider may choose to treat you with an infusion pump if you require continuous infusion of medications, nutrition, and/or other fluids. These uses of the B. Braun Space and Outlook Pumps have received premarket clearance from the FDA.

The B. Braun Space and Outlook Pumps have received an emergency use authorization (EUA) for the use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat patients of all ages with or suspected of having COVID-19 and to decrease the exposure of healthcare workers to such patients during the COVID-19 pandemic. The Infusomat Space Volumetric Infusion Pump System has also received an emergency use authorization for the use in ground medical transport.

### 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.

### What is an EUA?

The United States FDA has authorized emergency use of the B. Braun Space and Outlook Pumps for the tracheal delivery of continuous nebulized medications into a nebulizer to treat patients of all ages with or those

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- **Where can I go for updates and more information?** 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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# FACT SHEET FOR PATIENTS

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

April 13, 2020

## Coronavirus Disease 2019 (COVID-19)

suspected of having COVID-19 and to decrease the exposure of healthcare workers to such patients during the COVID-19 pandemic available under an emergency access mechanism called an 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 during the COVID-19 pandemic.

The use of the B. Braun Space and Outlook Pumps in 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 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 B. Braun Space and Outlook Pumps may be effective for use in the tracheal delivery of continuous nebulized medications into a nebulizer to treat patients of all ages with or those suspected of having COVID-19 and to decrease the exposure of healthcare workers to such patients may be effective in treatment of 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).

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- **Where can I go for updates and more information?** 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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