FACT SHEET FOR PATIENTS

Emergency Use of the B. Braun Space and Outlook Pumps During the COVID-19 Pandemic April 11, 2020

Coronovirus 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.

- **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. 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. BraunSpace 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

- **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.

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).

- **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.