B. Braun Receives FDA Emergency Use Authorization for Use of Infusion Pumps with Nebulizers to Treat COVID-19 Patients

Action Allows Perfusor® Space, Infusomat® Space, and Outlook® ES Pumps to be Used for Tracheal Delivery of Continuous Nebulized Medications into a Nebulizer

BETHLEHEM, PA – April 13, 2020 – B. Braun Medical Inc. (B. Braun) today announced that the US Food and Drug Administration (FDA) issued Emergency Use Authorization (EUA) of B. Braun’s Perfusor® Space Syringe Infusion Pump, Infusomat® Space Volumetric Infusion Pump, and Outlook® ES Pump systems for use in the “tracheal delivery of continuous nebulized medications into a nebulizer to treat patients of all ages with or suspected of having the Coronavirus Disease 2019 (COVID-19) and to decrease the exposure of healthcare providers (HCP) to such patients during the COVID-19 pandemic.”

“This authorization allows for an alternative method to administer continuous nebulized medications to patients who are critically ill with COVID-19, many of whom are on ventilation,” said Wes Cetnarowski, MD, Chief Medical Officer and Senior Vice President, Scientific Affairs at B. Braun. “As hospitals struggle to cope with the surge of patients suffering from this deadly disease, this action provides another tool for healthcare professionals on the front line to treat some of the most serious cases while helping to protect clinicians by reducing their exposure to infected patients.”

Studies have shown that using infusion pumps with nebulizers can help provide steady, controlled delivery of nebulized medication to patients with acute respiratory distress syndrome (ARDS). Some of the most critical COVID-19 patients suffer from severe ARDS.

“We applaud this decisive action taken by the FDA to help some of the most seriously ill COVID-19 patients,” said Jean-Claude Dubacher, Chairman and Chief Executive Officer of B. Braun Medical Inc. “The rapid review and authorization of this and other COVID-19 countermeasures demonstrate the agency’s commitment to ensure that healthcare providers have the medical devices and treatments they need to fight this disease.”

The EUA also authorizes ground medical transport use of the Infusomat® Space Volumetric Infusion Pump System. The Perfusor® Space Syringe Infusion Pump System is already cleared for ground transport.

B. Braun submitted the EUA request to FDA on April 8, 2020 under the agency’s January 2017 “Guidance for Emergency Use Authorization of Medical Products and Related Authorities,” which enhances FDA’s authority to support emergency preparedness and response and foster the development and availability of medical products for use in public health emergencies.

- The B. Braun Space and Outlook 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 Space and Outlook Pumps have been authorized for emergency use by FDA 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;

The B. Braun Space and Outlook 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.

Additional information is available on the Emergency Use Authorizations page of the FDA website and the COVID-19 Information page on B. Braun’s website.

About B. Braun

B. Braun Medical Inc., a leader in infusion therapy and pain management, develops, manufactures, and markets innovative medical products and services to the healthcare industry. Other key product areas include nutrition, pharmacy admixture and dialysis. The company is committed to eliminating preventable treatment errors and enhancing patient, clinician and environmental safety. B. Braun Medical is headquartered in Bethlehem, PA and is part of the B. Braun Group of Companies in the U.S., which includes B. Braun Interventional Systems, Aesculap® and CAPS®.

Globally, the B. Braun Group of Companies employs more than 64,000 employees in 64 countries. Guided by its Sharing Expertise® philosophy, B. Braun continuously exchanges knowledge with customers, partners and clinicians to address the critical issues of improving care and lowering costs. To learn more about B. Braun Medical, explore our website.

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