FACT SHEET FOR HEALTHCARE PROVIDERS

Emergency Use of Infusion Pumps and Infusion Pump Accessories **During the COVID-19 Pandemic**

Coronavirus Disease 2019 (COVID-19)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of infusion pumps and infusion pump accessories.

Certain infusion pumps and infusion pump accessories are authorized for emergency use by healthcare providers to treat conditions caused by the Coronavirus Disease 2019 (COVID-19) with the controlled infusion of medications, total parenteral nutrition (TPN), and/or other fluids. Controlled infusion means all programmable infusion modes such as continuous, intermittent, and bolus infusions. This Fact Sheet is specific to infusion pumps and infusion pump accessories that were authorized by FDA under an emergency use authorization (EUA) for these devices available at: https://www.fda.gov/media/138057/download.

All patients who are treated with authorized infusion pumps and infusion pump accessories during the COVID-19 pande will receive the Fact Sheet for Patients: Emergency Use of Infusion Pumps and Infusion Pump Accessories Duri the **COVID-19** Pandemic

What are the symptoms of VID-19? Many patients with confirmed Co 9 have d eloped fever and/or symptoms illnes acute respin e.g., cough, difficulty bre ng). The current into available to charz rize the spectrum of clinical maess JVID-19 sr associated with sts that symptoms ortness o eath or dyspnea, fever, include cough chills, myalgias, new loss of sore throat, lac taste or smell. Bas what is knov bout the virus that OVIDans and ptoms may after exposure to the da ar any e from 2 us. Based the median incubation preliminar period is an ximately 5 days, but may range 2-14 ays.

P٥ ealth officials have identified cases of COVID-19 broughout the world, including the United infec h may pose risks for public health. Please States,

May 13, 2020

check the CDC webpage for the most information.

pec

or

What do I need to know about e emergency use accessories? infusion pumps and infusion p

- Certain infusion pum and infu pump accessories that p specific crite or safety loriz performance, a abeling have beer or emergency j
- Infusion pt and infu pump accessories ed products are found in the aut ealthcare pr auth ed for u ers to treat COVID-19 cond ns caused the controlled or other fluids. infus of medicatio PN. oviders should review h device, health For e uctions for use, including device the in

ssing instructions (if abeling information. ole), and our

ate personal protective equipment when e app for included suspected of having COVID-19 as d in the DC Interim Infection Prevention and g for in out Recommendations for Patients with Confirmed Con virus Disease 2019 (COVID-19) or Persons Coro nvestigation for COVID-19 in Healthcare Settings Unde he 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 infusion pumps and infusion pump accessories? Potential benefits of infusion pumps and infusion pump accessories include:

- Controlled flow of medications, TPN, and/or other fluids into a patient.
- For infusion pumps with remote monitoring or remote manual control features or administration sets and other infusion pump accessories with increased length, maintaining a safe physical distance between the clinician and patient affected by COVID-19.

Report Adverse events, including problems with device performance, 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

Emergency Use of Infusion Pumps and Infusion Pump Accessories **During the COVID-19 Pandemic**

May 13, 2020

Coronavirus Disease 2019 (COVID-19)

Potential risks of infusion pumps and infusion pump accessories include:

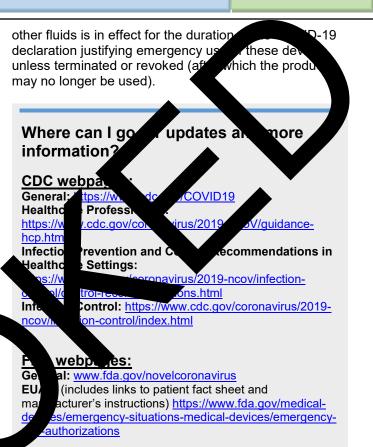
- Over or under delivery of therapy (especially medications).
- Other infusion delivery error, including free flow, and line occlusion.
- Air emboli.
- Pump programming error from remote manual controller malfunction.
- Delayed infusion resulting from faster battery depletion due to remote manual control functionality.
- Malfunction of infusion pump alarms and/or patient monitoring features.
- User error when healthcare providers may not be familiar with new pumps or new pump features.

What is an EUA?

The United States FDA has made certain infusion pumps and infusion pump accessories to treat co tions caused by COVID-19 with the controlled infusion medications, TPN, and/or other fluids available u er an emergency access mechanism called an nerae Use Authorization (EUA). The EUA is sup ted by Secretary of Health and Human Service's S's) declaration that circumstances exist to justif emergency use of medical devices, including ernative devices used as medical de due to short during the COVID-19 pademic.

usion pump accesson Infusion pumps and available under UA have pot undergone the same type of review an FDA-ap ed or cleared device. FDA may issu EUA w certain criteria are met, which includes the e no adequ approved, s, and base and ava ble alterr the totality of le, it is r sci nce av onable to believe nfusion io amp accessories that mps and ctive to treat conditions eet certain teria may be VID-19 with the controlled infusion of caused by edicat ther fluids.

A for infusion pumps and infusion pump Τĥ s to treat conditions caused by COVID-19 acce with the colled infusion of medications, TPN, and/or



Report Adverse events, including problems with device performance, 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