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)

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 pandemic will receive the Fact Sheet for Patients: Emergency Use of Infusion Pumps and Infusion Pump Accessories 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). The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, and new loss of taste or smell. 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 current information.

What do I need to know about the emergency use of infusion pumps and infusion pump accessories?

- Certain infusion pumps and infusion pump accessories that meet specific criteria for safety and performance, as labeling have been authorized for emergency use.
- Infusion pumps and infusion pump accessories found in the list of authorized products are authorized for use by healthcare providers to treat conditions caused by COVID-19 with the controlled infusion of medications, TPN, and/or other fluids.
- For each device, healthcare providers should review the instructions for use, including device specific reprocessing instructions (if applicable), and other labeling information.

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 Coronavirus Disease 2019 (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 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 conditions caused by COVID-19 with the controlled infusion of medications, TPN, and/or other fluids available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by 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.

Infusion pumps and infusion pump accessories available under an EUA 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 is no adequate, approved, and available alternative, and based on the totality of scientific evidence available, it is reasonable to believe that infusion pumps and infusion pump accessories that meet certain criteria may be effective to treat conditions caused by COVID-19 with the controlled infusion of medications, TPN, or other fluids.

The EUA for infusion pumps and infusion pump accessories to treat conditions caused by COVID-19 with the controlled infusion of medications, TPN, and/or other fluids 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).

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/hcp/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

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**