FACT SHEET FOR PATIENTS

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

May 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 a device, called an infusion pump, with the controlled infusion of medications, nutrition, called total parenteral nutrition or TPN, and/or other fluids.

This Fact Sheet contains information to help you understand the benefits and risks of using infusion pumps and infusion pump accessories (such as the tubing and catheters that allow the pump to deliver medication) for the controlled infusion of medications, TPN, and/or other fluids. 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.

After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your doctor, nurse, or other 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 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. The current information available to characterize the spectrum of clinical illness associated with COVID-19 symptoms that symptoms include cough, shortness of breath or difficulty breathing, fever, chills, muscle pain, headache, sore throat, or new loss of taste or smell.

What do I need to know about infusion pumps and infusion pump accessories?
A healthcare provider may choose to treat you with an infusion pump and infusion pump accessories if you require controlled infusion of medications, TPN, and/or other fluids. Controlled infusion means that the pump can be programmed to give you continuous (constant), intermittent (occasional), and bolus (a dose given at once) infusions. Infusion pumps are an integral part of patient care during the COVID-19 pandemic because patients undergoing mechanical ventilation, among other medical interventions, require controlled infusion using at least one infusion pump.

Certain infusion pumps and infusion pump accessories have been authorized under this EUA for emergency use by healthcare providers to treat conditions caused by COVID-19 with the controlled infusion of medications, TPN, and/or other fluids due to shortages.

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.

- **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.
- **Have a problem with device performance?** Report adverse events 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.

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You should discuss any questions or concerns with your health care provider. You have the option at any time to refuse or stop treatment with this device. If you choose to decline or stop treatment with this device, you should discuss any alternative treatment options with your healthcare provider.

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 (when air gets into the blood stream)
- Pump programming error from remote manu controller malfunction.
- Delayed infusion resulting from faster attery depletion due to remote manual contr functi ity.
- Malfunction of infusion pump alarms a or patie monitoring features.
- User error when healthcare providers ma ot be familiar with new pumps pump feat s.

What is an EUA?
The United States A has authorized emerge se of infusion pum nd infusion ump accessories to treat condition aused by C ID-19 with the controlled infusion of med ions, T , and/or other fluids available under a ncy access chanism called an EU the EUA is ported by the ecretary of He and man Ser 's (HH) declaration that c umstanc exist to jus the mergency use of medical dev s during the ID-19 pandemic.

These infusion pumps and infusion pum ories have not undergone the same type view as DA-approved or cleared device. FDA y issue an EU when certain criteria are met, w n includes that the are no adequate, approved, and ilable alternatives In addition, the FDA decis n is ba on the totality o scientific evidence avai e showing it is reasonable to believ at infusion pump nd infus pump accessories t meet certain criteria effective to trea nditions ca d by COVID with the controlled in n of m cations, TPN, and/or other fluids.

The EUA r infusion pu s and in on pump accesso s for COVID-19 t for the duration of the COV 19 declaration jus g emergency use of se de unless terminated or revoked (after which th odu s may be used).

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