Prefilled Saline Flush Syringe Conservation Strategies - Letter to Health Care Personnel

March 21, 2022

The U.S. Food and Drug Administration (FDA) is aware the United States is experiencing interruptions in the supply of prefilled 0.9% sodium chloride (saline) intravenous (IV) lock/ flush syringes. Prefilled 0.9% sodium chloride IV lock/ flush syringes are in shortage because of an increase in demand during the COVID-19 public health emergency, as well as recent vendor supply chain challenges, including the permanent discontinuance of certain prefilled saline lock/ flush syringes.

Recommendations

The FDA recommends health care personnel use prefilled 0.9% sodium chloride lock/ flush syringes, as your supply allows. When prefilled 0.9% sodium chloride lock/ flush syringes are not available, consider the following recommendations, including conservation strategies, to maintain the quality and safety of patient care:

- Use preservative-free, sterile 0.9% sodium chloride single dose vials if prefilled sterile 0.9% sodium chloride syringes are unavailable.
- Use heparin lock flush syringes, typically used to flush an IV catheter to help prevent blockage within the catheter after receiving an IV infusion, if medically appropriate and in accordance with your facility's policy, unless contraindicated in the manufacturer's labeling.
- Do not use expired prefilled saline flush syringes because they may have decreased volume, degraded ingredients, or lack sterility that may compromise the device's performance and increase patient risk.

- Do not use prefilled saline flush syringes that are not FDA-cleared flush syringes.
- Contact the FDA at deviceshortages@fda.hhs.gov as well as your group purchasing organization (GPO), local product representative, distributor, or account manager if the conservation strategies are not adequate to maintain sufficient supply.
- Consider recommendations from the FDA as well as relevant professional organizations for other strategies that might be appropriate for your organization.

Background

Prefilled 0.9% sodium chloride intravenous lock/ flush syringes are single use syringes filled with sterile 0.9% sodium chloride (saline) solution, which may come in different volumes. A prefilled 0.9% sodium chloride intravenous lock/flush syringe is used to help prevent vascular access systems from becoming blocked and to help remove any medication that may be left at the catheter site.

FDA Actions

On March 21, 2022, the FDA added prefilled 0.9% sodium chloride IV saline flush syringes (product code NGT - Saline, Vascular Access Flush) to the medical device shortage list and device discontinuance list. The device shortage list reflects the types of devices the FDA determined to be in shortage. The FDA will continue to update the list as needed. The FDA also carefully reviews each notification under section 506J of the Federal Food, Drug, and Cosmetic Act received and uses this information, along with any additional details about the supply and demand of a device, to determine whether a device is in shortage.

On January 14, 2022, the FDA updated the table of device types and corresponding product codes identified as devices that FDA believes are critical to the public health during the COVID-19 pandemic under section 506J(a)(1) of the FD&C Act to include prefilled saline flush syringes (product code NGT).

The FDA lists FDA-cleared prefilled saline flush syringes in the FDA's 510(k) Premarket Notification database under the product code NGT (Saline, Vascular Flush).

The FDA is working with manufacturers to help mitigate the shortage. The FDA continues to monitor the situation to help ensure prefilled 0.9% sodium chloride IV lock/ flush syringes are available for patients where intravenous infusions are medically necessary. The FDA will inform the public if significant new information becomes available.

Reporting Problems to the FDA

The FDA encourages health care personnel to report all adverse events or suspected adverse events experienced with any prefilled saline flush syringes.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program.
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations.
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

In addition, the FDA would like to hear from health care personnel who have trouble obtaining devices, as well as from other stakeholders who may help mitigate potential shortages. You may email the FDA at deviceshortages@fda.hhs.gov. Note that pursuant to section 506J manufacturers must notify the FDA of an interruption or permanent discontinuance likely to lead in a meaningful disruption in the supply of these devices.

Contact Information

If you have questions about this letter, contact the FDA about a medical device supply chain issue.

Content current as of:
03/21/2022

Regulated Product(s)
Medical Devices