DeRoyal Industries Recalls Surgical Procedure Packs for Mislabeled Lidocaine

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product

- DeRoyal Pacemaker Tray Pgybk
  - Lot Number 54239375, exp. 02/01/2022
- DeRoyal Heart Cath Procedure Pack
  - Lot Numbers: 54310362, exp. 01/01/2022; 54366825, exp. 01/01/2022
- DeRoyal Angio Cath Removal Tray
  - Lot Numbers: 54368716, exp. 06/01/2022
- Distribution Dates: April 19, 2021 to May 11, 2021
- Devices Recalled in the U.S.: 138
- Date Initiated by Firm: May 14, 2021

Device Use

DeRoyal Industries' surgical procedure packs include a set of devices that are used for routine cardiac procedures such as heart catheterizations, pacemaker-related procedures and x-ray heart imaging (angiogram) procedures.

Each pack listed above includes Hospira Pfizer 1% lidocaine, a local anesthetic that prevents or reduces pain by stopping nerves from sending pain signals during a surgical or catheter procedure.

Reason for Recall

DeRoyal is recalling the surgical procedure packs because the packs contain 1% lidocaine that has been mislabeled as 0.5% bupivacaine. Though both lidocaine and bupivacaine are local anesthetics, their dosing is different. If 1% lidocaine is given to the patient instead of 0.5% bupivacaine, the patient may be underdosed and experience pain during the procedure. If 0.5% bupivacaine is given to the patient instead of 1% lidocaine, it may cause an overdose of bupivacaine with potential life threatening or fatal consequences.

There have been no deaths, complaints, or reported injuries related to this issue.

This recall is related to a Hospira recall (/safety/recalls-market-withdrawals-safety-alerts/hospira-issues-voluntary-nationwide-recall-one-lot-05-bupivacaine-hydrochloride-injection-usp-and)for the same mislabeling issue.

Who May be Affected

- Health care providers using DeRoyal surgical procedure packs
- Patients who receive care using DeRoyal surgical procedure packs

What to Do

On May 14, 2021, DeRoyal sent an Urgent Recall Notice to affected customers and provided the following instructions:

- Identify affected surgical packs and discontinue their use
- Hold packs affected by this recall separately to ensure they are not used
- Complete a form (provided with the recall notice) to inform the company of affected products on hand, even if no products are found in inventory, and return it by fax to: 865-362-3716 or by email to: recalls@deroyal.com (mailto:recalls@deroyal.com).
- Return entire surgical packs to DeRoyal

Distributors were also asked to share information about this recall with their customers.

Contact Information

Customers with questions about this recall should email tmarsee@deroyal.com (mailto:tmarsee@deroyal.com).

Additional Resources:

For this recall:

- DeRoyal Heart Cath Procedure Pack Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=187487)
- DeRoyal Angio Cath Removal Tray Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=187488)
- DeRoyal Pacemaker Tray Pgybk Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=187486)

For the related Hospira recall:

- Hospira Issues A Voluntary Nationwide Recall for One Lot of 0.5% Bupivacaine Hydrochloride Injection, USP and One Lot of 1% Lidocaine HCl Injection, USP Due to Mislabeling (Parent firm for this recall) (/safety/recalls-market-withdrawals-safety-alerts/hospira-issues-voluntary-nationwide-recall-one-lot-05-bupivacaine-hydrochloride-injection-usp-and)

How do I report a problem?

Health care professionals and consumers may report adverse reactions or quality problems (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.