Smiths Medical Recalls Jelco Hypodermic Needle-Pro Fixed Needle Insulin Syringes for Skewed Graduated Marks on Syringe Barrel That May Cause Insulin Overdose or Underdose

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

- Jelco Hypodermic Needle-Pro Fixed Needle Insulin Syringes
- Models and Lot

Model Number	Name	Lot Number
4428-1	Jelco Hypodermic Needle-Pro Fixed Needle Insulin Syringe 28Gx1/2" 1CC	4046543, 4062235
4429-1	Jelco Hypodermic Needle-Pro Fixed Needle Insulin Syringe 29Gx1/2" 1CC	4014096, 4031846, 4031845, 4040734, 4043536, 4046545, 4046546, 4062239, 4062240, 4062238 and 406224

- Distribution Dates: October 31, 2020 to January 10, 2021
- Devices Recalled in the U.S.: 1,431,000
- Date Initiated by Firm: May 14, 2021

Device Use

The Jelco Hypodermic Needle-Pro Fixed Needle Insulin Syringe is a one-time use syringe used to draw and inject a common formulation of insulin (U-100) into a patient.

Reason for Recall

Smiths Medical is recalling the affected products because these insulin syringes may have graduated markings that are printed incorrectly on the syringe barrel. Specifically, the "odd numbered" graduation markings on the syringe barrel may be skewed approximately 20 degrees

upward. If the skewed markings are used to measure an insulin dose, patients may receive too much or too little insulin. This overdose or underdose of insulin can lead to serious patient harm, including death.

There have been nine complaints, no injuries, and no deaths reported for this issue.

Who May be Affected

- Health care providers using affected Jelco Hypodermic Needle-Pro Fixed Needle Insulin Syringes
- Patients who require care using affected Jelco Hypodermic Needle-Pro Fixed Needle Insulin Syringes

What to Do

On May 17, 2021, Smiths Medical sent an urgent medical device recall notice to distributors and clinical users of the Jelco Hypodermic Needle-Pro Fixed Needle Insulin Syringe. The letter requested that customers:

- Locate affected product in your possession by referring to the Affected Devices List.
- Determine the number of affected devices in your possession and complete the Response Form. Return the form to fieldactions@smiths-medical.com (mailto:fieldactions@smiths-medical.com) whether or not you have affected products in your possession.
- Return all affected products for processing. A prepaid label will be provided after Smiths Medical receives the completed response form.

The letter requested that device distributors share the medical device recall notice with any customers who may have received potentially affected products.

Contact Information

Customers who have questions about this recall should email fieldactions@smiths-medical.com (mailto:fieldactions@smiths-medical.com).

Additional Resources:

- Medical Device Recall Database Entry (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=187480)
- Press Release from Smiths Medical (https://www.smiths-medical.com/en-us/company-information/news-and-events/news/2021/june/17/recall-of-jelco-hypodermic-needle-pro-fixed-needle-insulin-syringe) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)

How do I report a problem? Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program using an online form, regular mail, or FAX.