

# Caution When Using Pen Needles to Inject Medicines: FDA Safety Communication

## Date Issued

September 27, 2018

## Audience

- Patients and caregivers who use or are considering using pen injectors with pen needles to inject prescription medicines.
- Health care providers who treat patients, or who train users on pen needles and pen injectors

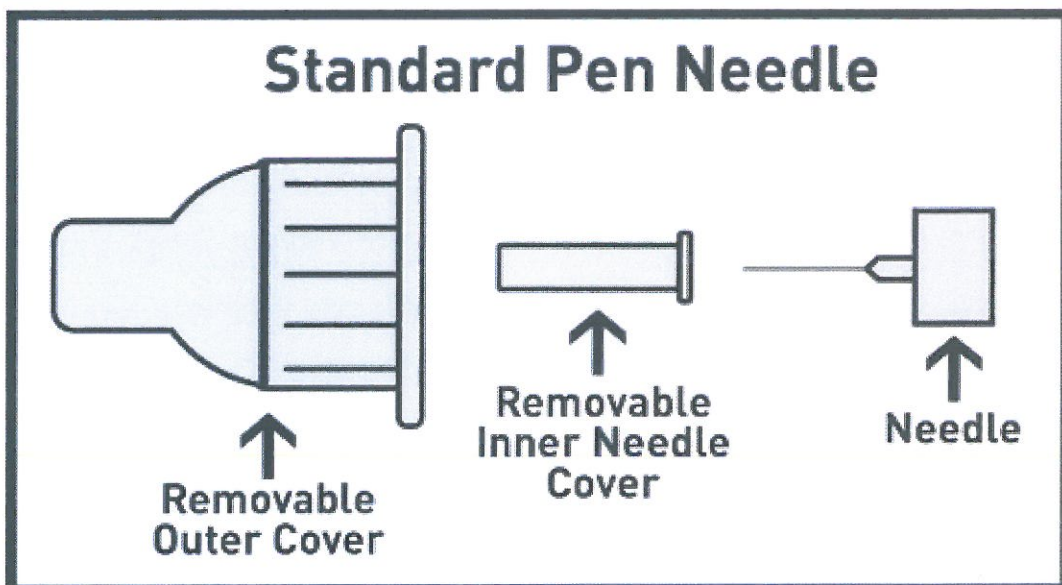
## Specialties

Health care providers including Nurses, Nurse Practitioners, Physician Assistants, Health Educators, Pharmacists, and Physicians

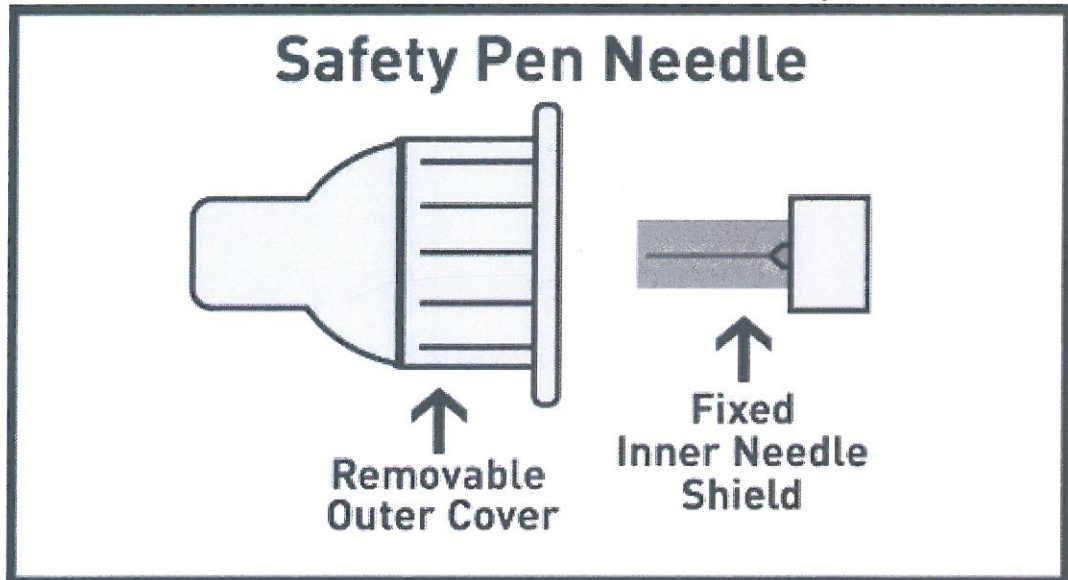
## Device

Pen needles are used to inject medicine with pen injectors. For example, when insulin is packaged in a multi-dose pen injector, a new pen needle is used each time to inject the insulin.

Common types of pen needles include standard pen needles and safety pen needles. **Standard pen needles** often have an outer cover and a removable inner needle cover, which are both removed before an injection. **Safety pen needles** are different. They have an outer cover that is removed, and a fixed inner needle shield that is not removed before an injection.



Standard pen needles often have an outer cover and a removable inner needle cover. Both the outer cover and the inner needle cover must be removed before an injection.



Safety pen needles have an outer cover and a fixed inner needle shield (sharps injury prevention feature). The outer cover is removed before an injection, but the fixed inner needle shield is NOT removed before an injection.

## Purpose

The FDA is providing recommendations to patients, caregivers, and health care providers to promote the safe use of pen needles used to inject medicines from pen injectors.

## Summary of Problem and Scope

Pen needles are used with pen injectors to inject different types of medicines. The same pen injector can be used with both standard and safety pen needles. It is possible that patients could be taught using one type of pen needle, then receive the other type later. This could cause confusion about how to use the pen needle correctly, and may prevent the patient from getting the medicine they need.

The FDA has received reports of patients using standard pen needles to inject insulin without removing the inner needle cover. In these cases, the inner cover stopped the needle from entering the skin and the patients did not get the insulin. Some patients developed high blood sugar (hyperglycemia) because the inner needle cover stopped them from getting insulin. One patient was hospitalized and died because of having blood sugar that was too high for too long.

To help people use pen needles safely, the FDA recommends these actions:

## Recommendations for Patients and Caregivers

- Each time you get a new box of pen needles, check to see if they are the same type as the ones you were trained to use. If not, ask your health care provider to show you how to use this new type properly.
- If you use a standard pen needle with an outer cover and an inner needle cover, be sure to remove both covers before use.

- If you feel like your medicine from the pen injector is not working, talk to your health care provider.
  - For example, if you have diabetes and your blood sugar levels are high after insulin injections, contact your health care provider to talk about your injection technique, insulin dosage, and other things that can affect your blood sugar levels.
- If you have any questions about your pen needle, contact your health care provider.

## Recommendations for Health Care Providers and Health Care Educators

- Train and educate patients and caregivers:
  - Show them how to use the pen needle for their medication.
  - Ensure they can demonstrate correct technique to verify proper use of their pen needles.
  - Be sure they are aware of the different types of pen needles, and they know which type they use.
  - Explain the signs and symptoms of under-dose (and over-dose) of their medication, how to monitor their medical condition (for example, blood glucose levels), and when to contact their health care provider.
- **Prescribers:** Consider whether there could be a problem with an injection or medication administration technique before changing a medication dose.
- **Pharmacists:** When dispensing a new box of pen needles, consider asking the patient if they know how to use the type of pen needles being dispensed.
  - For example, remind patients that:
    - For standard pen needles with an outer cover and an inner needle cover, remove both covers before use.
    - For the safety pen needle, remove only the outer cover, as the fixed inner needle shield remains in place.
  - Be available to answer questions from patients and caregivers or refer them to their applicable health care provider.

## FDA Activities

The **[FDA asked pen needle manufacturers \(/downloads/MedicalDevices/Re-sourcesforYou/Industry/UCM621797.pdf\)](https://www.fda.gov/medicaldevices/re-sourcesforyou/industry/ucm621797.pdf)** to review their most recent labeling (that is Instructions or Directions for Use) and training materials to assess the need for updates to clearly explain how to use the pen needle safely. In addition, the FDA requested that standard pen needle manufacturers consider adding a warning in the labeling regarding the need to remove both the outer cover and the inner needle cover before use.

## Reporting Problems to the FDA

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect or experience a problem with a pen needle, we encourage you to file a voluntary report through **[MedWatch \(http://www.fda.gov/Safety/Med-Watch/HowToReport/default.htm\)](http://www.fda.gov/Safety/Med-Watch/HowToReport/default.htm)**, the FDA Safety Information and Adverse Event Reporting program. Be sure to include:

- Device manufacturer and model of the pen needle

- The name of the medication being delivered through the pen needle (for example, the name of the pen injector)
- A clear description of event or issue and any applicable patient outcomes

Device manufacturers and user facilities must comply with the applicable **[Medical Device Reporting \(MDR\) regulations](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)**. (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>)

Health care personnel employed by facilities that are subject to the **[FDA's user facility reporting requirements](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm)** (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm>) should follow the reporting procedures established by their facilities.

## Other Resources

- **[Institute for Safe Medical Practices, Severe Hyperglycemia in Patients Incorrectly Using Insulin Pens at Home](https://www.ismp.org/alerts/severe-hyperglycemia-patients-incorrectly-using-insulin-pens-home)** (<https://www.ismp.org/alerts/severe-hyperglycemia-patients-incorrectly-using-insulin-pens-home>)
- Truong, T. H., Nguyen, T. T., Armor, B. L., & Farley, J. R. (2017). **[Errors in the Administration Technique of Insulin Pen Devices: A Result of Insufficient Education](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5380504/)** (<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5380504/>). *Diabetes Therapy*, 8(2), 221–226. <http://doi.org/10.1007/s13300-017-0242-y>
- **[American Diabetes Association](http://www.diabetes.org/)** (<http://www.diabetes.org/>)
- **[NIH - Diabetes](https://medlineplus.gov/diabetes.html)** (<https://medlineplus.gov/diabetes.html>)

## Contact Information

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at **[DICE@FDA.HHS.GOV](mailto:DICE@FDA.HHS.GOV)** (<mailto:DICE@FDA.HHS.GOV>), 800-638-2041 or 301-796-7100.

**[More in Safety Communications](/MedicalDevices/Safety/AlertsandNotices/default.htm)**  
(</MedicalDevices/Safety/AlertsandNotices/default.htm>)

**[2018 Safety Communications](/MedicalDevices/Safety/AlertsandNotices/ucm592582.htm)** (</MedicalDevices/Safety/AlertsandNotices/ucm592582.htm>)

**[2017 Safety Communications](/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)** (</MedicalDevices/Safety/AlertsandNotices/ucm553873.htm>)