



October 04, 2018

Dear Valued Customer:

BD is committed to providing patients with safe and effective products, and we stand by the performance and integrity of every product we manufacture, including all pen needles and safety pen needles, which have a long history of customer satisfaction.

Therefore, we are taking prompt action due to the Safety Communication entitled "Caution When Using Pen Needles to Inject Medicines: FDA Safety Communication" released by the United States Food and Drug Administration on September 27, 2018.

The FDA Safety Communication provides: "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."

Before issuance of this Safety Communication, BD Diabetes Care had updated its label and instructions for use (IFU) of certain BD pen needles to include clear graphics describing how to remove both the outer cover and inner needle shield before use. All BD standard pen needle products have an opaque colored inner needle shield, which must be removed prior to injecting insulin. Enclosed, please find a sample IFU for review.

While BD Diabetes Care has not been made aware of any concerns with BD product specifically, BD will continue to evaluate this Safety Communication, engage with FDA on next steps and will take any action as appropriate.

Ensuring the safety and quality of our products is our top priority at BD, and we are dedicated to maintaining a robust quality system to fulfill this commitment.

If you have concerns regarding this matter please contact our customer service center on: +1-888-232-2737, or email: diabetes@bd.com

Sincerely,

A handwritten signature in black ink that reads "Michele Wootten". The signature is written in a cursive, flowing style.

Michele Wootten
WW Vice President Quality Management, BD Diabetes Care
BD

How to inject with a Pen Needle



1. Wash hands. Remove seal and push the new needle straight onto the pen. Do not put the needle on at an angle. Screw on tight. Remove outer cover.



2. Remove needle inner shield.



3. Check the flow of medication by dialing 2 units until you see a drop of medication.



4. Inject straight in.*

*Patients ages 2-6, or those who are extremely lean may require a pinch-up.



5. Post-injection, count for 10 seconds before removing from skin to help ensure an accurate dose.



6. Use **once** and dispose of properly. Do not leave pen needle attached causing an open passage for air.

For additional information, visit bd.com/sharpsdisposal

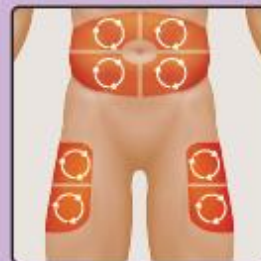
Practice Healthy Injection Site Rotation



Injection sites:
Front



Injection sites:
Back



Rotate both between
and within sites



When returning to an injection site, inject at least one finger width away from your last injection.

Replace Your Needle Every Time You Inject



• Do not leave pen needle attached causing an open passage for air.



• Do not resheath used needles.