

ASSURE[®] ID

+ DUO PRO and PRO SAFETY PEN NEEDLES

TRAINING GUIDE



ARKRAY cares about the health and well-being of your patients.

arkray USA, INC.⁺
Your Diabetes Health Ally

Instructions for Use Training Guide

Assure® ID DUO PRO and Assure® ID PRO Safety Pen Needles



Supplies needed: safety pen needle and pen injector with insulin.

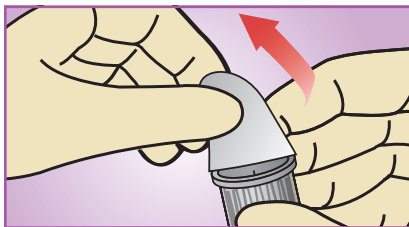
As a healthcare provider taking care of persons living with diabetes and requiring insulin injections, quality safety pen needles and safe usage are critical to effectively manage their diabetes.

- + Keep this sheet handy to ensure you are using Assure ID Safety Pen Needles correctly.
- + Before injection, be sure to read the user instructions for the pen injector device for proper use and control of insulin flow. If you are using the pen injection device for the first time and have questions, please contact the manufacturer.

Indications for Use/Intended Use for Assure ID Safety Pen Needles

Assure ID Safety Pen Needles are disposable, sterile needles intended for use with a pen injector device for the subcutaneous injection of insulin.

Attaching the needle to the pen injection device

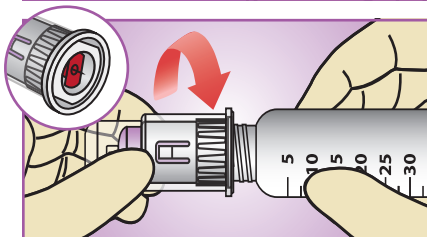


Step 1

Remove the seal from the safety pen needle.

For your safety

- + Once the seal is removed, **do not** place fingers on the back end of the needle to avoid a needle stick.
- + **Do not** remove the ClearPrime™ safety cover from the safety pen needle until instructed to do so.



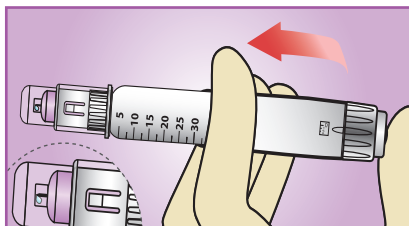
Step 2

Attach the safety pen needle securely to the pen injector device by twisting clockwise until it stops. When using the Assure ID PRO safety pen needle, there will be no connection-end safety shield.

For your safety

- + **Do not** remove the ClearPrime™ safety cover as it serves as a safety shield to prevent a needle stick before injection. The cover should remain intact until ready to inject.

Priming the pen injection device



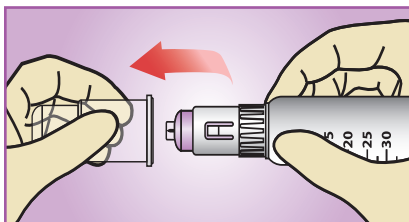
Step 3

Prime the pen injector device according to the pen injector device instructions for use.

For your safety

- + **Do not** remove the ClearPrime™ safety cover as it serves as a safety shield to prevent a needle stick before injection. The cover should remain intact until ready to inject and during transportation to the patient's side.

Performing the injection

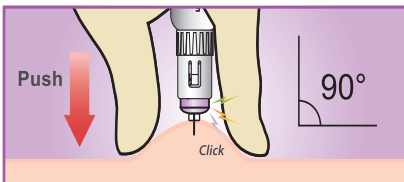


Step 4

When ready to inject, remove the safety cover from the safety pen needle to expose the needle.

For your safety

- + **Do not** place your fingers on the front end of the needle to avoid a needle stick.



Step 5

Inject into the skin as recommended by your physician with or without a skin lift.

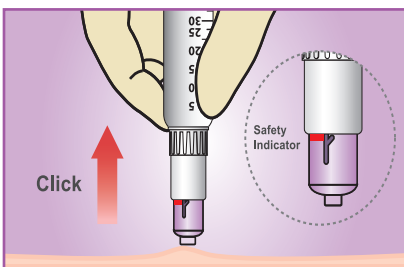
For your safety

- + Do not place your fingers on the front end of the needle to avoid a needle stick.



Step 6

Hold the injection for 5 to 10 seconds before withdrawal as recommended by your physician to ensure delivery of the full dose and to prevent leakage of medication.

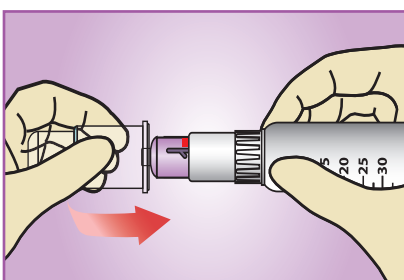


Step 7

Remove the safety pen needle by lifting straight-up from the injection site. The patient-end safety mechanism is activated automatically when needle is withdrawn from the skin.

For your safety

- + Do not remove the needle at an angle.
- + The automatic patient-end safety shield will engage and cover the needle when you lift the pen injection device from the patient's skin.
- + Do not place fingers on the front end of the needle to prevent a needle stick.
- + Do not twist on the safety shield at any time.

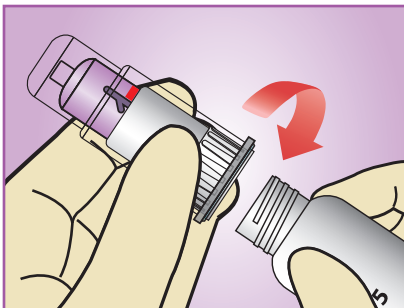


Step 8

Attach the cover securely by pushing cover over the patient-end safety shield.

For your safety

- + Do not grasp or twist on the patient-end safety shield or the lower white barrel of the safety pen needle at any time to prevent damage to the safety mechanism and to prevent a needle stick.
- + Do not remove the needle before placing the cover back on the shielded needle.



Step 9

Remove the safety pen needle from the pen injector device by twisting counter-clockwise. The pen connection-end safety shield will automatically engage when removed to assist in needlestick prevention. Dispose of in a sharps container. When using the Assure ID PRO safety pen needle, there will be no connection-end safety shield.

For your safety

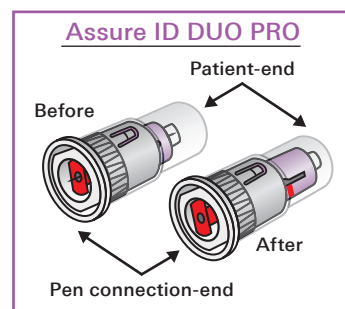
- + The pen connection-end safety shield will automatically engage when the needle is removed from the pen injector device (DUO PRO only).
- + Do not grasp the needle by the back end at any time to prevent a needle stick.

Precautions

- + Safety pen needles are for self-injection and professional use.
- + Safety pen needles are single use only. Always use a new, sterile safety pen needle. Do not reuse to avoid cross-contamination.
- + Store safety pen needles in a cool and dry place.
- + Do not use the safety pen needles if the cover is missing or loose.
- + Avoid contaminating the safety pen needle with hand lotion, oils, dirt, or debris.
- + Safety pen needles should be disposed of in an appropriate sharps container.
- + Do not use the safety pen needles past the expiration date noted on the seal or carton.

Important Safety Information

- + Before injection, consult the pen injector device manual to establish correct insulin amount.
- + Do not use if the protective seal is missing or loose, or the needle is bent or damaged.
- + Consult with your physician before changing pen needle lengths.

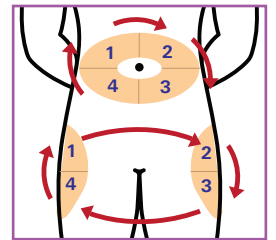
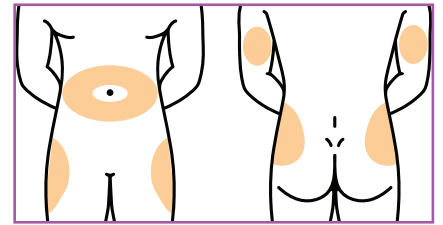


Injection Tips

According to the Mayo Clinic Proceedings, a healthy injection routine includes proper site selection, site rotation and injection technique.¹ Choosing a healthy routine may reduce discomfort and complications.

Site Selection and Rotation

- + Clean the injection site and inject with clean hands to avoid contamination.
- + You can inject insulin into the fatty tissue of the abdomen, buttocks, back of upper arm or the outer side or front of the upper thigh as shown in the diagram.
- + Injections into the upper arm or the inner side of the upper thigh are not recommended as the risk of injecting into a muscle is higher in these body regions.
- + Change the injection site often to avoid tissue hardening.
- + Within the site you choose, you should also systematically rotate where you inject to avoid lipohypertrophy. Spacing injections at least 1 cm is recommended.
- + It may be beneficial to develop an easy-to-follow scheme for rotating injections within the site, such as clockwise.¹



Injection Techniques

Injection without a skin fold at a 90° angle.

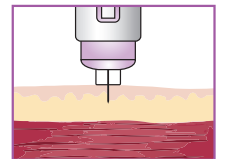
With shorter needles, such as the Assure ID DUO PRO 31G x 5mm and the Assure ID PRO 30G x 5mm safety pen needle, it is recommended that you inject vertically into the skin (at a 90° angle) without a skin fold to prevent injecting too deep and into the muscle tissue.¹

Injection timing recommendations.

The thumb button should only be pressed after the pen needle is fully inserted. After the thumb button is completely pushed in, slowly count to 10 and then withdraw the needle from the skin. Some patients may need more than 10 seconds, especially when giving higher doses. Counting only to 5 may be acceptable for lower doses.¹

Post-injection advice.

After injection, needles should be removed from the pen and disposed of immediately. This prevents air and other contaminants from entering the cartridge and medication from leaking out.¹



Features

Assure ID Safety Pen Needles, with ClearPrime™ safety cover, are sterile, non-pyrogenic, for single use only and may be used with most universal threading pen injector devices.

Pen Injection Devices Compatible with Assure ID Safety Pen Needles

Sanofi Aventis	ClikSTAR®, SoloSTAR®, JuniorSTAR®
Lilly	KwikPen®, Humalog® Pen, HumaPen Memoir®, HumaPen Luxura® HD, HumaPen Luxura®, HumaPen® Savvio®, HumaPen Ergo® II
Novo Nordisk	FlexTouch®, NovoPen® 3, 4 and 5, Innolet®, FlexPen®, Victoza®, NovoPen Echo®
Owen Mumford	Autopen® Classic, Autopen® Junior
Berlin Chemie	BerliPen® Areo, BerliPen® Junior

1. Mayo Clin Proc. September 2016;91(9):1231-1255.