DEKA DKPI-09233-001 Twiist Automated Insulin Delivery System Owner's Manual

Contents

DEKA

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Specifications

- Model: Twiist Automated Insulin Delivery System
- Cassette Fill Volume: 100 Units to 300 Units

Product Usage Instructions

Scan Cassette:

1. Tap Scan Cassette and position the QR code on the bottom of the cassette inside of the green box.
2. If you have already used the cassette, a Cassette Already Used notice is displayed. Tap OK and get a new cassette package.

Fill the Cassette

1. Follow the insulin manufacturer's instructions for handling and use
2. Allow insulin to adjust to room temperature before filling the cassette.
3. Wipe the top of the insulin vial with an alcohol wipe.
4. Open a new syringe and needle.
5. Attach the needle to the syringe luer connector by twisting until the finger is tight.
6. Remove the cap from the needle and pull the syringe plunger out to the amount needed to fill the cassette.
7. Insert the needle into the vial.
8. Press down on the syringe plunger to inject air into the vial, pressurizing it.
9. While still holding the syringe, flip the vial so it is above the syringe and slowly pull down on the plunger to fill the syringe with the amount you had selected during the cassette setup.
10. Remove the needle from the insulin vial.
11. Gently insert the needle straight into the cassette filling port. Do not force the needle.
12. Push the syringe plunger down to fill the cassette. Keep holding the plunger down as you remove the needle.
13. With the needle pointing upward, and still inserted in the vial, tap on the syringe to remove any visible air bubbles.
14. Dispose of the used needle and syringe in a Sharps Container. Contact your local authorities to determine the proper method for disposing of needles and syringes.

Sequel Med Tech announced its partner DEKA R&D has earned U.S. Food and Drug Administration (FDA) 510(k) clearance for its twist automated insulin delivery (AID) system powered by Tidepool. According to the company, the Twiist AID system is the first drug delivery system that directly measures the volume and flow of insulin delivered with every micro-dose. It's cleared for type 1 diabetes patients aged six and up and offers the ability to address individual dosing needs.AID systems combine data from a continuous glucose monitoring (CGM) device, a control algorithm, and an insulin pump to automate insulin delivery. The Twiist AID system leverages the FDA's medical device interoperability standards to help patients better tailor their treatments. Its Tidepool Loop technology lets the system automatically adjust insulin delivery based on CGM readings and predicted glucose levels.

"The clearance of the twist AID system is a pivotal first step in Sequel's quest to make day-to-day life easier for people with type 1 diabetes. The tTwiistsystem combines drug delivery technology that directly and precisely measures each dose of insulin, providing the opportunity for better control and flexibility," said Sequel CEO and co-founder, Alan Lotvin, MD. "Sequel is working to simplify living with diabetes by introducing product and process innovation while expanding access for all. It's why we expect to distribute Twiist through the pharmacy channel so more people with type 1 diabetes have a convenient, affordable way to get started on an AID system. As we get closer to launch, we will share more details about additional initiatives designed to expand access and simplify the

patient experience. The underlying drug delivery technology was developed by DEKA R&D, founded by American inventor and entrepreneur Dean Kamen. Kamen helped commercialize the first wearable insulin pump for diabetes while still in high school. He's a co-founder of Sequel.

"The FDA's clearance marks a transformative moment, and we would like to thank the FDA for its vision of interoperability in insulin delivery that will help improve diabetes therapies for years to come. The Twiist system was designed from the start to integrate with the latest available innovation, and it represents the next generation of insulin delivery," said Kamen. "The twist AID system reimagines how insulin is measured and delivered for more personalization with a simpler design. I believe the twisted system will set a new standard for precise, dependable insulin delivery going forward."

Frequently Asked Questions

Q: What should I do if the pump fails to beep during self-test?

A: Discontinue the system and switch to your backup insulin therapy plan if this occurs.

Q: Can I fill the cassette with cold insulin?

A: No, filling the cassette with cold insulin may result in delivery errors that can be harmful.

Q: Is it safe to fill a cassette before using it?

A: No, do not fill a cassette before you plan to use it as it may result in spoilage or changes to insulin potency or purity, leading to harm.

Q: Should I connect the infusion set tubing while filling or priming the cassette?

A: No, do not connect infusion set tubing during filling and priming as it may lead to an unintended overdose of insulin causing low blood glucose.

Documents / Resources

	DEKA DKPI-09233-001 Twiist Automated Insulin Delivery System [pdf] Owner's Manual DKPI-09233-001 Twiist Automated Insulin Delivery System, DKPI-09233-001, Twiist Automated Insulin Delivery System, Insulin Delivery System, Delivery System, System

References

- **User Manual**