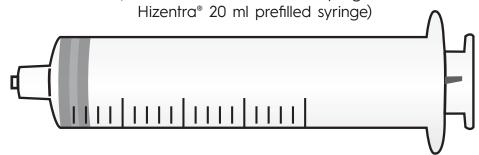
Freedom Edge® SubQ Infusion Mat

Gather Supplies:

Use this area to lay out your infusion supplies.

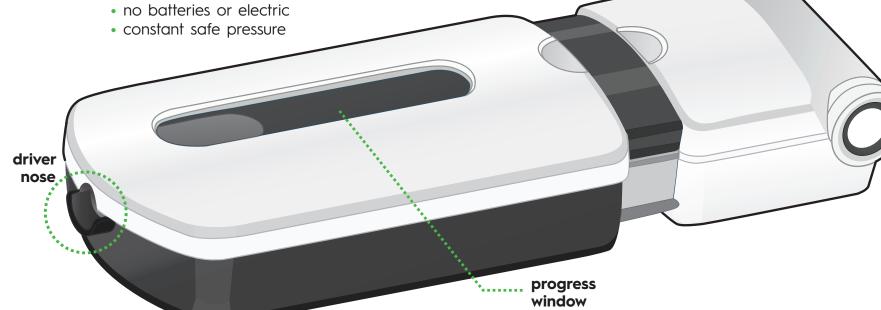
Medication Syringe(s)

(BD® Luer-Lok® 20 or 30 ml syringe or Hizentra® 20 ml prefilled syringe)



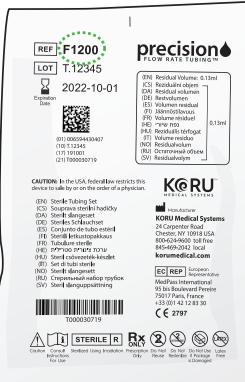
FreedomEdge Syringe Driver

• completely portable system • no batteries or electric



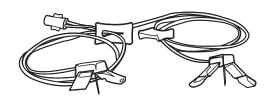


Precision Flow Rate Tubing™ (check the F number of the tubing)





Scan code for Freedom **Training Videos**



HIgH-Flo Subcutaneous Safety Needle Sets™



Medication Spike or Needle

Alcohol/Chlorhexidine Pads





Use **ONLY** Freedom System accessories manufactured by KORU Medical Systems (Precision Flow Rate Tubing sets and HIgH-Flo Subcutaneous Safety Needle Sets) with the FreedomEdge syringe driver. Use of off-brand products may result in unknown flow rates.

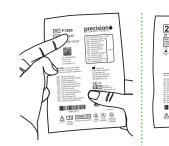
Prepare System & Prime Tubing:

Make sure to thoroughly read every step prior to starting your infusion.



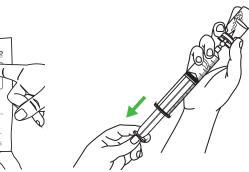
Sanitize

Clean your infusion work surface with alcohol or disinfectant soap and water. Wash your hands thoroughly and, if required, put on disposable gloves. Lay out your infusion supplies.



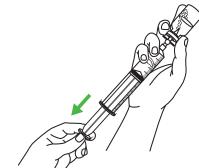
2 Verify Tubing/Needles

Verify that you are using the correct Precision Flow Rate Tubing and HIgH-Flo Needle Sets prescribed by your healthcare provider. Inspect the tubing and needle sets. If damaged, replace and contact your healthcare provider.



3 Fill Syringe

Ensure the medication is at room temperature. Refer to the drug manufacturer's instructions or ask your healthcare provider for detailed filling instructions. If using a prefilled syringe, go to **Step 4**. If using vials, fill the BD 20 or 30 ml syringe(s) with the required dose.



5 Priming Tubing

Always follow your healthcare provider's protocol. Grasp the medication syringe and gently press down on the plunger with steady pressure. Focus on a single needle and try to stop the flow when the fluid approaches the needle. Be careful not to prime to the needle tip. Release pressure from the plunger to stop the flow.



1. Remove sterile caps from opposite end of tubing set and HIgH-Flo needle set and connect, using care not to contaminate ends. 2. Remove the sterile cap from the luer disc end of the Precision tubing set and connect to syringe.

4 Attach Tubina



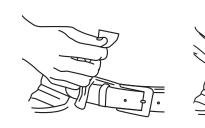
• It is recommended to insert the needles dry to minimize site irritation.

• To best see the medication, prime the tubing against a solid-colored surface in a well-lit area.

Use the provided red grea to prime your needles against:



Insert Needles:



• Prepare Sites

Select your site(s), cleanse with alcohol and let dry. Carefully remove shield from the needle tip, with care not to touch needle.



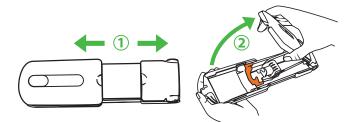
90° angle.



Peel the printed side from the dressing to expose adhesive. Secure the needle by placing the adhesive dressing in the center of the needle butterfly. Smooth it outward over skin.

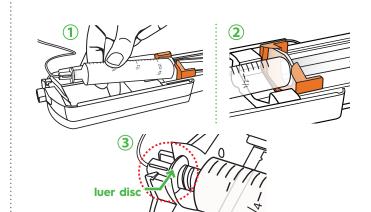
NOTE: Refer to your drug package insert to see if checking for blood return is a required step. If checking for blood return, please see the FreedomEdge Instructions for Use for additional steps.

Load FreedomEdge:



9 Open Syringe Driver

1. To open the FreedomEdge, pull firmly to extend until you hear a click. 2. Then, lift the top lid by releasing each side from the base and fully open.



10 Load Prepared Syringe

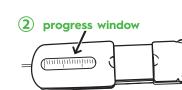
1. With syringe gradations facing up, push the syringe flange against the orange syringe locater, sliding it back slightly. 2. Make sure the syringe flange is seated within the front part of the syringe locater.

3. Verify that the Precision tubing (with the luer disc) is connected to syringe. Seat the luer disc inside the syringe driver nose so that the syringe is firmly seated inside the syringe driver. If needed, pull back on the syringe locator to help seat the luer disc into the syringe driver's nose.

NOTE: You should not need to use significant force to load or remove the syringe. You can test proper fit by gently tugging on the syringe. It will stay in place if properly attached.

Starting & Ending Infusion:





Begin Infusion

1. To begin, close the top lid. The infusion will begin immediately.

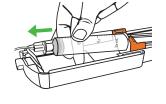
2. Periodically monitor the infusion by checking the progress window. To pause infusion: Simply open the syringe driver. To continue, re-close the top lid.

NOTE: When closing the syringe driver, make sure that the top lid is fully extended and aligns with the bottom portion.

If using multiple syringes: Once the first syringe is empty, open the FreedomEdge. Remove the syringe and connect additional syringe to the luer disc end of the Precision tubing set. Load the syringe and close the syringe driver to continue infusion.

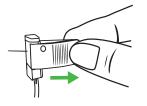
12 End of Infusion

Once syringe is completely empty and the infusion is complete, open the top lid to turn the FreedomEdge OFF. Remove the empty syringe and its tubing.



13 Remove Needle(s)

Holding the needle in place, peel back the surrounding adhesive dressing. Remove the needle in a straight motion. Close the wings over the needle and snap shut. If needed, cleanse each insertion site and cover with a bandage.



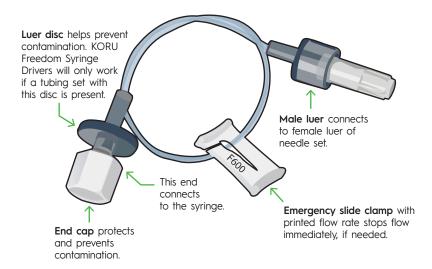
14 Discard Supplies & Clean

Discard all supplies as instructed. Wipe down the syringe driver (refer to Instructions for Use for complete cleaning procedure).



Precision Tubing

Precision Flow Rate Tubing™ controls your flow rate and infusion time. Each tubing set provides a different level of flow restriction. This, plus the viscosity of the drug, provides a precise delivery for predictable and consistent infusions.





We offer twenty variations of Precision tubing, so that you can get the infusion rate you need. Ask your healthcare provider to help determine which flow rate tubing is best for you.

Don't forget your Precision!

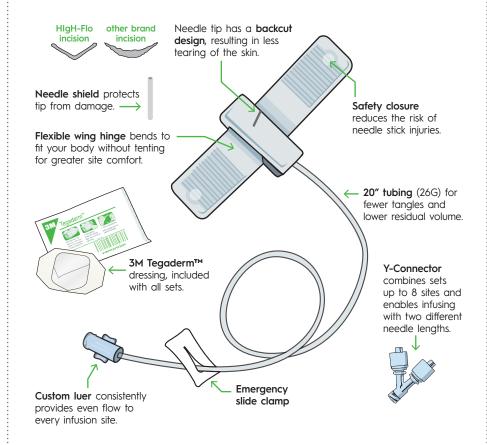
Do not connect your HIgH-Flo safety needle set directly to the syringe without a Precision flow rate tubing set attached.





HIgH-Flo Needles

Specifically made for subcutaneous administration, our HIgH-Flo Subcutaneous Safety Needle Sets™ are designed for greater comfort and dependable flow throughout a patient's infusion.

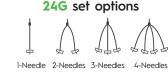


Options for every 'body'

HIgH-Flo needles are available in 26 and 24 gauge for maximum comfort and flow. We offer lengths from 4 mm to 14 mm in configurations of 1 to 6 needle sets.





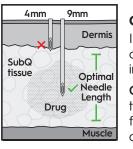


Optimizing your Infusion Experience

Quality of life can be enhanced with the proper training and ancillary supplies. Infusion optimization is possible through several variables. Some variables that impact patient tolerability include:

- Infusion site selection and volume infused per site
- · Optimal needle length in relation to the amount of subQ tissue and body shape
- Number of needles
- Infusion flow rate
- Pump type (mechanical vs. electrical)
- Initial vs. subsequent infusion parameters (Always check your drug package insert for dosing information)

Minimizing Site Reactions



Consider trying a longer needle

If the selected needle is too short and the opening is too close to the dermis, site irritation and leaking may occur.

Generally: small children use 4 mm, children (up to age 9) and patients with extremely low body fat use 6 mm, over age 9 and adults use 9 mm and/or 12 mm, and very large adults use 14 mm.

Inquire about adding/changing infusion sites

Consider adding infusion sites to spread out the medication volume per site. Make sure to select sites that have an adequate amount of subQ tissue. Avoid scar tissue, muscle, hardened or

bruised areas. Rotate infusion sites if recommended by your healthcare provider. Periodically returning to sites that worked well in the past may provide best results.

Ask to try a slower flow rate tubing

Selecting the proper Precision Flow Rate Tubing is important when starting your therapy. It may be trial and error to find which flow rate works best for you.

- ▶ For patients who want to decrease overall infusion time. increasing the flow rate is recommended.
- For patients experiencing site reactions, it is recommended to decrease the flow rate.

Be sure the needle is dry upon insertion

Patients have found that inserting needles wet with medication can be irritating to the skin. Inserting the needles dry may result in less pain and irritation. If any medication gets on the needle tip, do not touch the needle. Allow the needle to dry for a few minutes before insertion.

Be aware of dressing/tape sensitivities

If you are a patient with dry or sensitive skin and find that the 3M Tegaderm™ (included with HlaH-Flo needle sets) is irritating, you may need to try different dressings, paper tape, or a cloth wrap. Ask your provider for suggestions.

▶ To avoid skin irritation and release the Tegaderm adhesive, pull and stretch it out horizontally parallel to skin. Any redness to the skin should be temporary.

NOTE:

- Always refer to your drug package insert for initial dosing parameters and special instructions.
- Site reactions in new patients will typically diminish over time as the subQ depots become more developed.

SubQ Injection Sites

The abdomen is the most common place to infuse, but ask your provider about your best site options.





infusion sites to find your best results.





Some medications require that sites be at least 2 inches (5 cm) apart check your package insert. Needles should be dry and inserted at a 90° anale. Talk to your healthcare provider about if and how to rotate

A Balanced Infusion

Did you know that Freedom syringe drivers are designed to slow down the infusion based on how well your body absorbs medication? This benefit, known as **DynEQ®** (**Dynamic equilibrium**), responds to infusion site pressure build-up to deliver a safe pressure throughout the infusion.

Q. When would I use HIgH-Flo 24 gauge needles vs. 26 gauge?

A. 26G is sufficient to administer a 20% solution (i.e. Cuvitru® and

Q. What is the least painful way to insert HIgH-Flo needles?

making this procedure easy.

Each site should be about 2" (5 cm) apart and needles should be inserted

at a 90° angle. Make sure any alcohol has evaporated off your sites, and

insert all needles dry. If needed, talk to your healthcare provider about

A. We offer 20 flow rates, suitable for delivering IgG and antibiotics, for

your healthcare provider to determine what flow rate works best for you.

A. You need a restrictive tubing with a disc luer. This ensures that your

Q. Is there a best way to remove the needles and dispose of them

A. If you are unsure of how to handle used needles, ask your healthcare

provider to demonstrate. HIgH-Flo has built-in safety. Just 'snap shut' by

pressing the wings together at ends to entrap the needle and then

dispose of the set. Needle sets should be disposed of in a standard

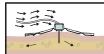
infusion is delivered at a controlled rate, and that the syringe stays

a variety of time frames ranging from a few minutes to days. Talk to

Q. Why can't I connect the needle set directly to the syringe?

Hizentra®), depending on system configuration. To achieve faster flow

rates, a 24G needle would be recommended. Always refer to the drug



trying a premedication.

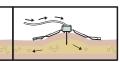
properly seated in the driver.

when I am done with an infusion?



manufacturer's package insert for infusion parameters.

Q. What flow rates are currently available?



A. Many patients tell us that they grab the wings

above the needle, tightly pinch the skin at the site

motion. HIgH-Flo butterfly wings are very flexible,

close together between their fingers, and insert the

needle straight into the pinched area with a dart-like

Troubleshooting



NOTE: For complete instructions, please refer to the FreedomEdge Instructions For Use.

korumedical.com/freedomedgeifu

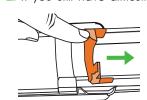
Swelling, pain or redness at the site

Numerous factors may contribute to infusion site reactions, such as: needle tip design, length, number of sites, flow rate, and dressing/covering. 1. Be sure to insert your subQ needles dry. Medication can irritate the skin. 2. Assure that the needles you are using are the correct length so that they reach your subQ layer.

- 3. Ask your provider about trying a slower rate tubing set, especially for your first few infusions.
- 4. If you've been having difficulty with rotating sites, consider returning to the sites that work best for you. Talk to your provider about options.

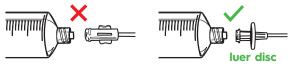
Syringe will not load or remove from the syringe driver You should not need to use significant force to load/remove a syringe.

1. Make sure the top lid is fully open. 2. If you still have difficulty, use one hand to slide back the syringe locator.



Syringe is not properly seated in the driver nose

1. Make sure you have not attached the HIgH-Flo needle set directly to the syringe.



2. Check that you are using a Precision tubing set (with the luer disc). 3. Make sure that the luer disc at the end of the tubing is properly seated in the nose of the syringe driver.



No flow

1. Make sure all slide clamps are open (unclamped). NOTE: A slide clamp should only be used in the case of an emergency to stop flow immediately. 2. Use sterile procedures to disconnect the tubing set from the needle set and check for medication drip. If medication drips from the tubing, it may be a problem with the needle set. If the medication does not drip, replace

3. With the FreedomEdge empty, open and close the lid, watching that the syringe pusher slides freely and does not bind.

the tubing as it may be damaged.

Slow flow

1. Confirm you are using the correct size syringe. 30 ml syringes flow approximately 20% slower

than 20 ml syringes on the same Precision flow rate tubing.

2. Administration may be slow based on how well the medication is absorbed through your tissue. If this is your first subQ infusion, it may take longer than expected because your body may need to adjust.

3. Avoid placing needles near/on top of areas of scar tissue or muscle. 4. It is possible you may need more sites, longer needles or a faster flow rate tubing set.

Leakage at the site

There are several factors to consider when overcoming drug leakage, including: needle length, location of infusion sites, number of infusion sites, flow rate and needle dressing.

- 1. If the selected needle is too short, leaking at the site may occur. Talk to your healthcare provider about trying a longer need
- 2. It is important that the site(s) you choose have a good amount of subQ tissue. Ask your healthcare provider if changing infusion sites and/or increasing sites would be beneficial.
- 3. You may want to try a slower flow rate tubing set. Ask your healthcare provider about your options.
- 4. Ensure you are using infusion site dressing to hold the needle in place.

Freedom Q&A

Q. How can I find my best infusion sites?

A. Simply time your infusions. Note how long the first half of your dose takes, and then the second half. Compare both times. If the second half takes longer, you may be able to find sites that accept the drug more easily. If the two times are almost equal, it means your sites are accepting the drug well, and the site pressure is not increasing over the duration of your infusion.



Q. Is my Freedom pump working? How can I tell if I am infusing?

A. Note the start time of the infusion and watch that the syringe plunger moves in accordance with your estimated infusion time. If you expect your dose to take 1 hour, then after 15 minutes, 1/4 of your dose should be complete. If there is any doubt, please ask your healthcare provider.

Q. What applications can the FreedomEdge be used for?

A. The FreedomEdge can be used to administer intravenous antibiotics and subcutaneous medications that will fit in a 20 or 30 ml syringe. For further details, please see the Indications for Use provided in the FreedomEdge Instructions for Use.

Q. How do I administer smaller or larger amount of fluid?

A. For smaller volumes, the system will automatically adjust to whatever amount is contained in the syringe. If a dose is larger than 30 ml, you can load an additional syringe using the same tubing and needle set.

Q. What if I want my infusion to go faster?

A. Talk with your healthcare provider to see if a change in ancillary supplies is appropriate. You may consider trying a faster flow rate tubing set and/or adding an infusion site.

Q. Does the FreedomEdge need maintenance?

A. The FreedomEdge's design is made to withstand day-to-day home use without any scheduled maintenance. In addition, there are no user serviceable parts inside. You should never attempt to open the rear housing or interfere with the syringe pusher of the FreedomEdge. If you experience a problem with your syringe driver, talk to your healthcare provider.

Q. How do I clean the FreedomEdge?

A. You can use a soft cloth dampened with a weak mixture of mild detergent and warm water (minimum ratio of 1 part detergent to 50 parts water by volume) to wipe areas that are accessible. Refer to the Instructions for Use for the full cleaning procedure.

Q. What is the temperature range that I can infuse in?

A. For accuracy and safety, most medications must be delivered at room temperature, but make sure to check the drug's package insert.

Q. What affects the flow rate of the FreedomEdge?

A. The two main factors are the diameter of the tubing and the viscosity of the fluid. Flow rates can also be affected by temperature, patient conditions, height differences between the system and infusion site, and excessive motion during infusion.

Q. Why are they called HIgH-Flo "safety" needle sets? A. The butterfly wings 'snap shut' at the ends, to cover the needle after use. This feature is designed to help prevent accidental needle-stick injuries.







KORU is a Proud Sponsor of the IDF

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