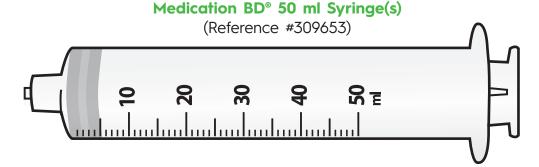
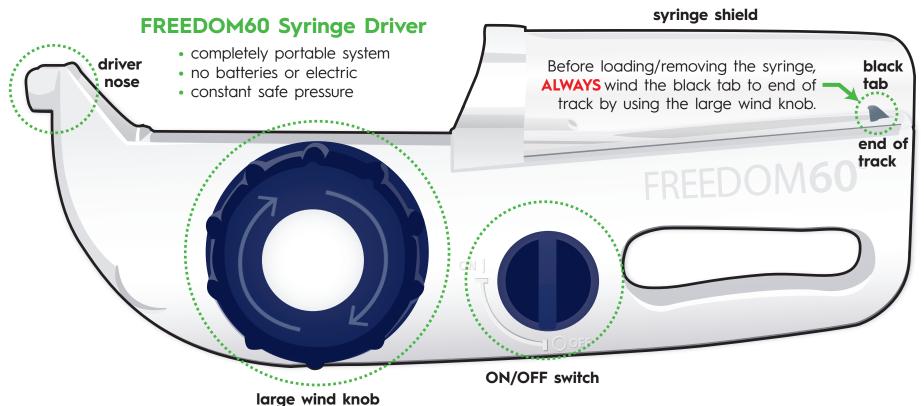
FREEDOM60[®] SubQ Infusion Mat Syringe Infusion System

Gather Supplies:

Use this area to lay out your infusion supplies.







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





Scan code for Freedom **Training Videos**



HIgH-Flo Subcutaneous Safety Needle Sets™





Alcohol/Chlorhexidine Pads

Medication

Spike or Needle





Use **ONLY** Freedom System accessories manufactured by KORU Medical Systems (Precision Flow Rate Tubing sets and HIgH-Flo Subcutaneous Safety Needle Sets) with the FREEDOM60 syringe driver. Use of off-brand products may result in unknown flow rates.

Prepare the Freedom System:

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.

4 Attach Tubing

tubing set and connect to syringe.



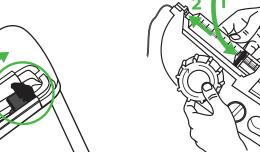
2 Verify Tubing & Needles

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



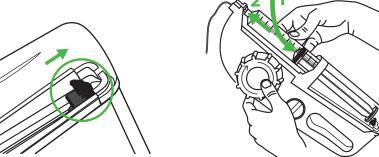
3 Prepare Syringe(s)

Be sure the medication is at room temperature before filling the BD 50 ml syringe(s) with your required dose. Refer to the manufacturer's instructions or ask your provider for more detailed filling instructions.



5 Check Black Tab

1. Remove sterile caps from Make sure the syringe driver is OFF and that the black tab inside the end of tubing set and HIgH-Flo needle set and connect, using clear syringe shield is at the end of care not to contaminate ends. its track. If the black tab is not at 2. Remove the sterile cap from the end of its track, wind the large the **luer disc** end of the Precision knob clockwise.



Insert Syringe

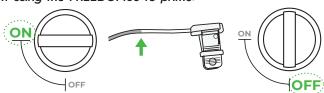
With syringe gradations facing up, 1. load the syringe and its tubing into the syringe driver and 2. make sure the luer disc is fully seated in the

Prime Tubing:

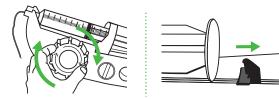
Always follow your provider's protocol. Priming can be done by hand or by using the syringe driver. Focus on a single needle and try to stop the flow when the fluid approaches the needle. Be careful not to prime to the needle tip.

7 Fill Tubing

If using the FREEDOM60 to prime:

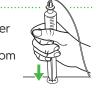


1. Turn the syringe driver's ON/OFF switch to the ON position to prime the tubing. Watch the tubing fill as the medication approaches the needle. Turn the syringe driver OFF.



plunger, until the black tab is at the end of its track.

If priming by hand: Push the syringe plunger and watch the tubing fill as the medication approaches the needle. Release pressure from the plunger to stop the flow.



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

To best see the medication, we suggest priming the tubing against a solid-colored surface in a well-lit area. Black or red work best. Use the area below to prime your set against:

Insert Needles:



8 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.

10 Secure



9 Insert

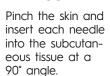
Peel the printed side from the dressing to expose adhesive. Secure the needle by placing the adhesive dressing in the

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 FREEDOM60 Instructions for Use for





driver OFF and wind the black tab to the end of its track. Remove the syringe from the syringe driver and disconnect from tubing. With aseptic technique, connect the additional syringe to the luer disc end of the Precision tubing set. Load the prepared syringe into the syringe driver. Turn the syringe driver ON to continue infusion. Repeat until total dosage is complete.

If using multiple syringes: Once the first syringe is empty, turn the syringe

Starting & Ending Infusion:



Begin Infusion

If you checked for blood return, re-insert the syringe into the syringe driver. Turn the

ON/OFF switch to the ON position. Periodically check that the syringe driver is working properly

by seeing that the syringe plunger is moving.

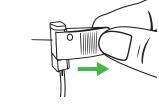
Turn OFF & wina Back

When the syringe is completely empty and total dosage is administered, turn the syringe driver OFF. Wind the large knob until the black tab is at the end of its track.



14 Remove Syringe

Pull syringe away from the syringe driver's nose and remove. If needed, cleanse each site and cover with a bandage.



13 Remove Needle(s)

Holding the needle in place, peel back surrounding adhesive dressing. Remove needle(s) in a straight motion, opposite the direction you inserted it. To use the safety feature, close wings over the needle and snap shut.



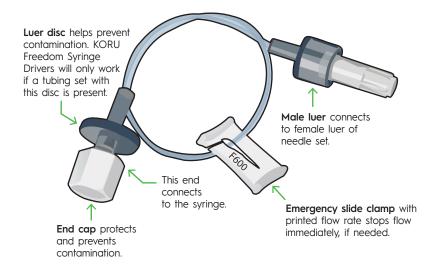


Discard Sharps ■ & Disinfect

Discard all sharps and supplies as instructed by your healthcare provider. Inspect the syringe driver for soil and wipe it down to ensure it is clean. Refer to the cleaning section in your Instructions For Use manual for details.

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.

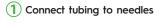




We offer twenty variations of Precision tubing, so that you can get the infusion rate you need. Ask your healthcare provider to help determine which flow rate tubing is best for you.

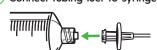
Don't forget your Precision!

If you accidentally connect your HIgH-Flo safety needle set directly to the syringe without a Precision flow rate tubing set attached, the FREEDOM60° will eject the syringe.



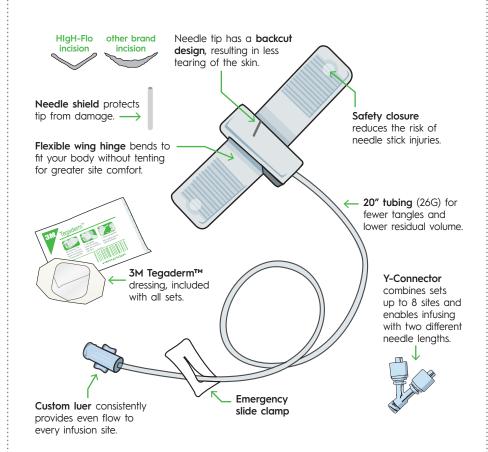
1 Connect tubing to needles 2 Connect tubing luer to syringe





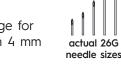
HigH-Flo Needles

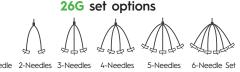
Specifically made for subcutaneous administration, our HIgH-Flo Subcutaneous Safety Needle Sets™ are designed for greater comfort and dependable flow throughout a patient's infusion.



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.





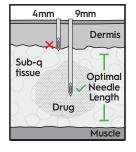
24G set options

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 sub-q 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 sub-g 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 HIgH-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 sub-q 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.







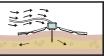


side of upper hip

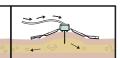
Some medications require that sites be at least 2 inches apart - check your package insert. Needles should be dry and inserted at a 90° angle. Talk to your healthcare provider about if and how to rotate infusion sites to find your best results.

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.







Troubleshooting

NOTE: For complete instructions, please refer to the FREEDOM60 Instructions For Use.

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.

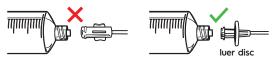
- 1. Be sure to insert your subcutaneous needles dry to avoid irritation. 2. Assure that the needles you are using are the correct length so that they reach your subQ layer.
- 3. Ask your provider about trying a slower rate tubing set, especially for your first few infusions.
- 4. If you've been having 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. Make sure the driver is in the OFF position and that the black tab is at the end of its track. If the black tab is not at the end of its track, wind the large knob so that the black tab is all the way back and try again.

Syringe will not stay inside of the syringe driver

1. Ensure the HIgH-Flo needle set is not directly connected 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. Assure that the syringe driver is in the ON position.

2. Make sure all slide clamps are unclamped. NOTE: A slide clamp should only be used in the case of an emergency to stop flow immediately. 3. 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 the tubing as it may be damaged.

Slow flow

- 1. Administration may be slow based on how well the medication is absorbed through your tissue. If this is your first sub-q infusion, it may take longer than expected because your body may need to adjust.
- 2. Avoid placing needles near/on top of areas of scar tissue or muscle. **3.** It is possible you may need more sites, longer needles or a faster flow rate tubing set.

Flow continues when the syringe driver is turned OFF

This is a normal function of the syringe driver. It is designed to maintain pressure during and after the infusion to prevent blood/drug return. To stop flow:

1. Make sure the syringe driver is turned to the OFF position. To release pressure from the syringe plunger, wind the large knob clockwise so that the black tab is at the end of its track.

2. You can also use the slide clamp to cut off flow immediately. This should only be done in the case of an emergency as use of the slide clamp may damage the tubing.

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 needle.
- 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. What's the noise the syringe driver creates when I first turn it on?



A. You will hear a 'whirring' noise as the black tab makes its way down the track. Once the black tab engages with the syringe plunger and the infusion begins, the noise will stop, and the infusion will be silent.

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

A. Check that the pump winds properly and makes a distinctive 'whirring' noise when turned on - this means it is working. Then, note the start time of the infusion and watch that the syringe plunger moves in accordance with your estimated infusion time. If in doubt, contact to your healthcare provider.

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.



1st half:

Q. How do I administer a dose larger or smaller than 50 ml?

A. If the dose is larger than 50 ml, you can load an additional syringe using the same tubing and needle set. For smaller volumes, the syringe driver will adjust to whatever amount is contained in the syringe. We also offer the FreedomEdge®, which is designed for smaller volumes and accommodates both 20 ml and 30 ml syringes.

Q. Can I over-wind the FREEDOM60?

A. No. When the black tab reaches the track end, the syringe driver is fully wound, and the large wind knob will start to make a clicking sound. If for any reason your FREEDOM60 will not wind, make sure the switch is OFF. If it is off and still won't wind, it may be damaged. Talk to your provider about a replacement.

Q. What applications can the FREEDOM60 be used for?

A. The FREEDOM60 can be used to administer intravenous antibiotics and subcutaneous medications that will fit in a BD® 50 ml syringe. For further details, please see the Indications for Use provided in the FREEDOM60 Instructions for Use.

Q. What happens if I turn the large wind knob during an infusion? A. Nothing. The wind knob is disengaged while the syringe driver is in the ON position. There is no effect by turning the knob in either direction.

Q. Does the FREEDOM60 need maintenance?

A. The FREEDOM60'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 syringe driver. If you experience a problem with your pump, talk to your provider.

Q. How do I clean the FREEDOM60?

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 affects the flow rate of the FREEDOM60?

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.

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 Hizentra®), depending on system configuration. To achieve faster flow rates, a 24G needle would be recommended. Always refer to the drug manufacturer's package insert for infusion parameters.

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



A. Many patients tell us that they grab the wings above the needle, tightly pinch the skin at the site close together between their fingers, and insert the needle straight into the pinched area with a dart-like motion. HIgH-Flo butterfly wings are very flexible, making this procedure easy.

Each site should be about 2" 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 trying a premedication.

Q. What flow rates are currently available?

A. We offer 20 flow rates, suitable for delivering IaG and antibiotics, for a variety of time frames ranging from a few minutes to days. Talk to your healthcare provider to determine what flow rate works best for you.

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

A. You need a restrictive tubing with a disc luer. This ensures that your infusion is delivered at a controlled rate, and that the syringe stays properly seated in the driver.

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. Is there a best way to remove the needles and dispose of them when I am done with an infusion?

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 sharps container





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