

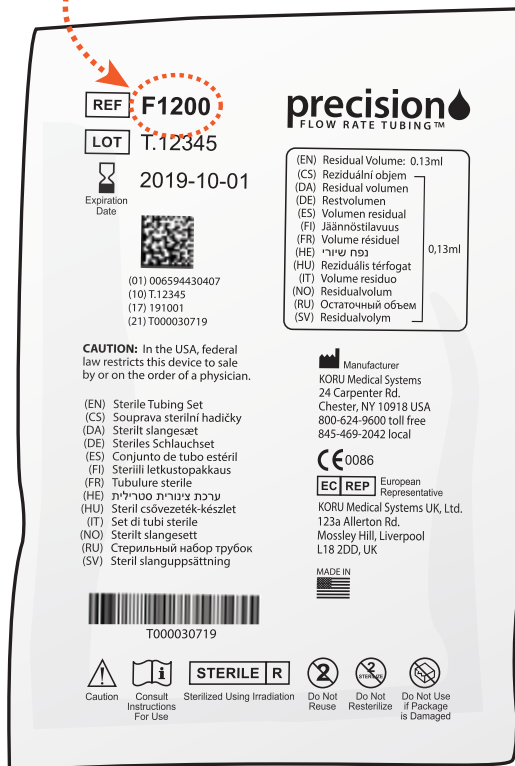
FREEDOM60[®] Syringe Infusion System

SCIg Infusion Mat

Wipe down reusable infusion mat with alcohol pad prior to each use.

Gather Supplies:

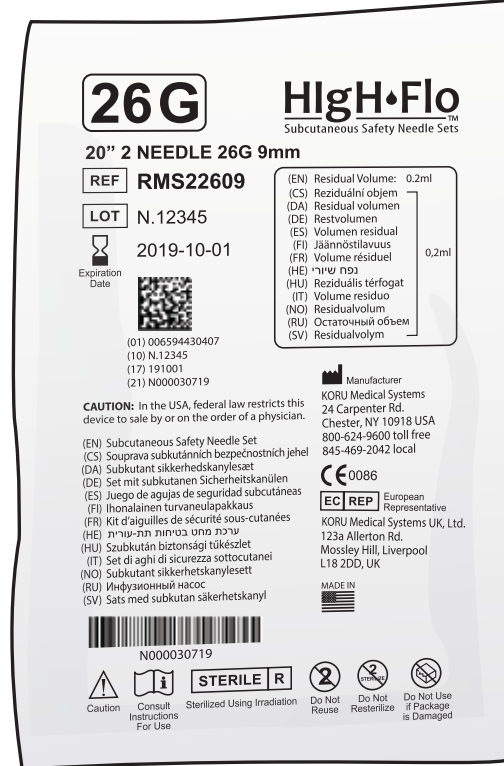
Precision Flow Rate Tubing™
(check the F number of the tubing)



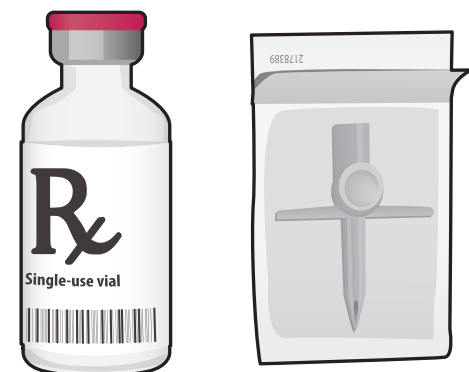
Alcohol/Chlorhexidine Pads



High-Flo Subcutaneous Safety Needle Sets™



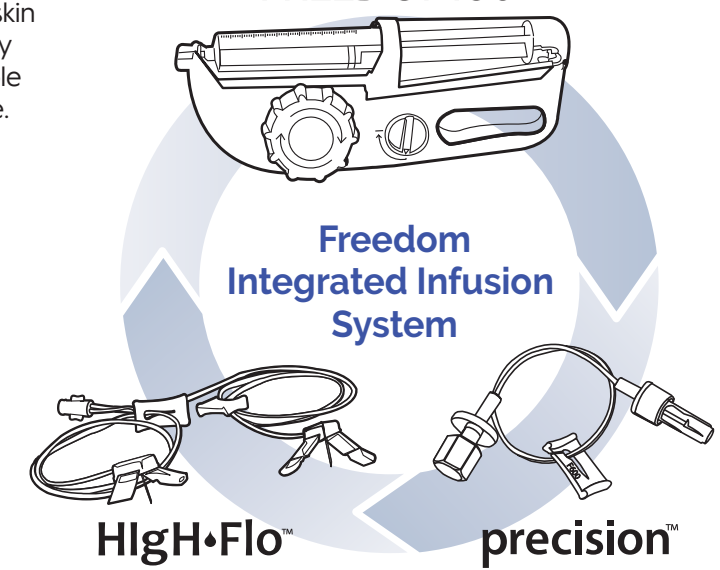
Medication Spike or Needle



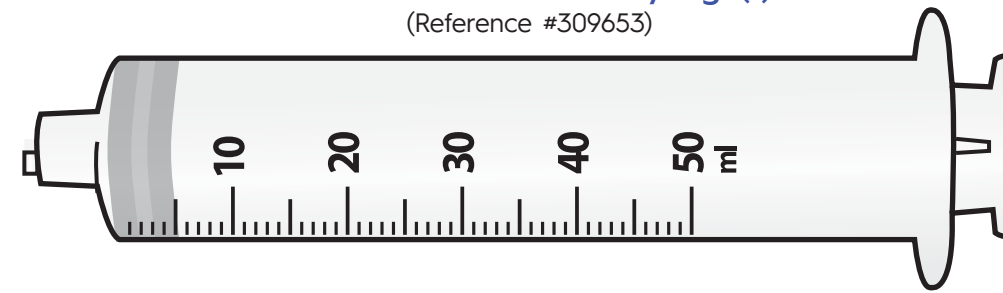
Why SCIg?

Sub-q immunoglobulin is infused slowly into the fatty layer under the skin as opposed to IVIg, which is delivered through a vein. SCIg is typically administered on a more frequent basis than IVIg, which provides stable blood levels, decreases side effects and improves overall quality of life.

FREEDOM60[®]

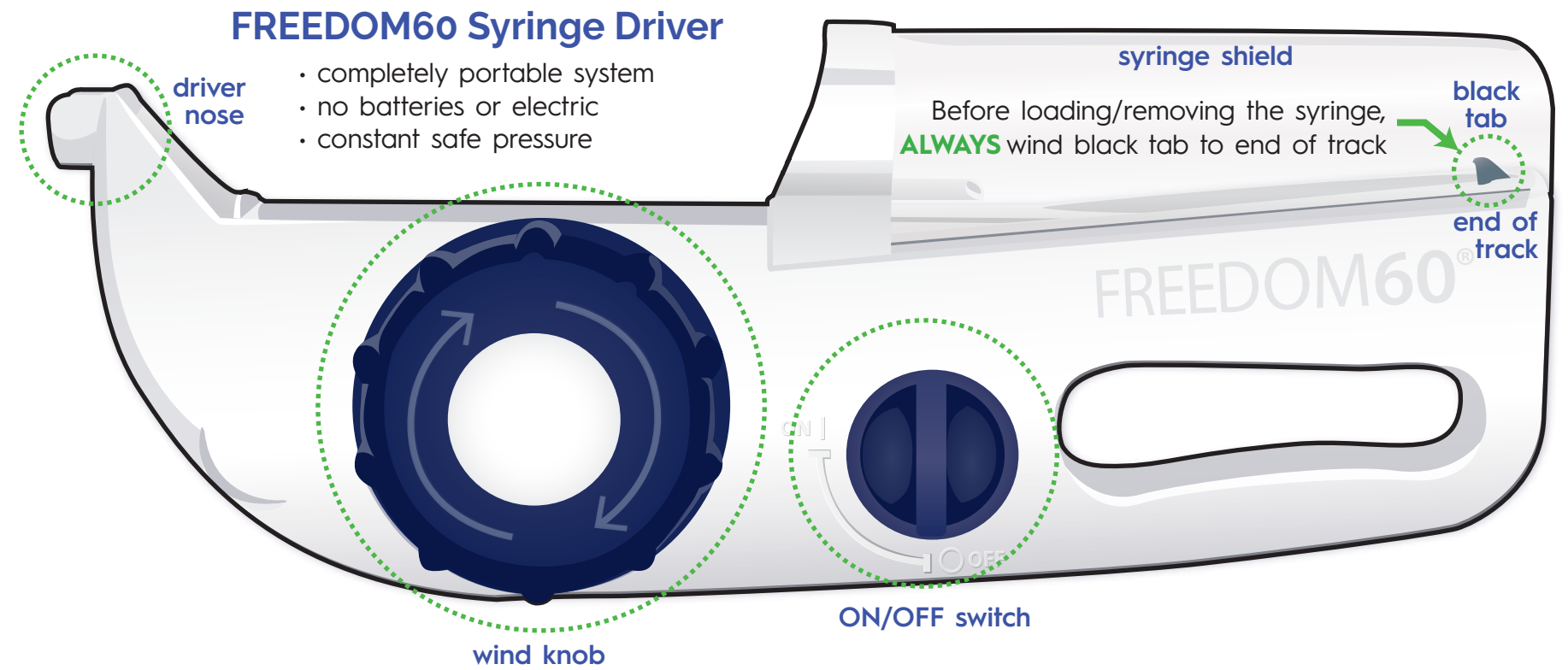


Medication BD[®] 50 ml Syringe(s)
(Reference #309653)



FREEDOM60 Syringe Driver

- completely portable system
- no batteries or electric
- constant safe pressure



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 Syringe Driver:

1 Wash Hands



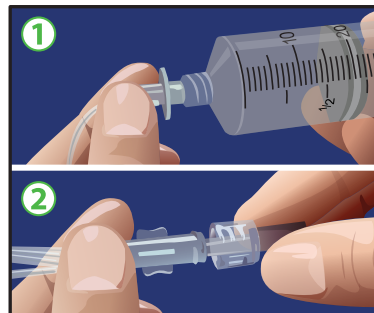
Wash your hands thoroughly and, if required, put on disposable gloves.

2 Fill Syringe



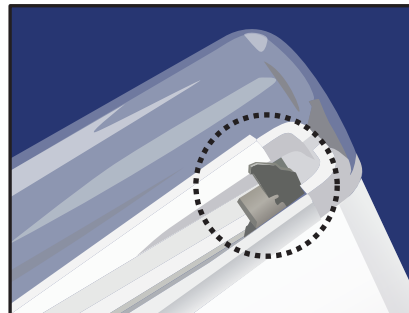
Be sure the medication is at room temperature before filling the BD 50 ml syringe with your required dose. Refer to the manufacturer's instructions or ask your provider for more detailed filling instructions.

4 Attach Tubing



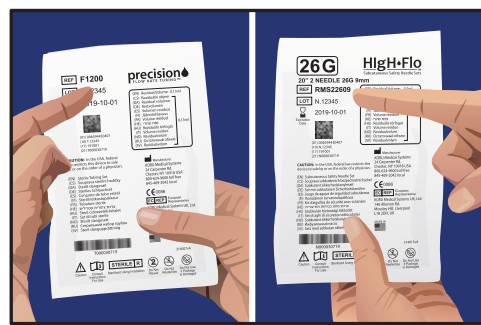
1. Remove the sterile cap from the luer disc end of the Precision tubing set and connect to syringe.
2. Remove sterile caps from opposite end of tubing set and High-Flo needle set and connect, using care not to contaminate ends.

5 Check Black Tab



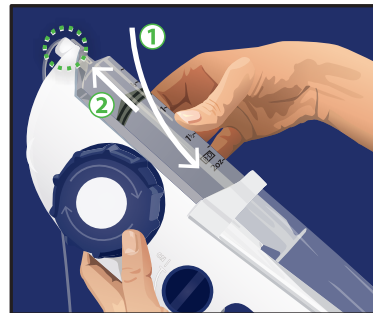
Make sure the syringe driver is off and the black tab inside the clear syringe shield is at the end of its track. If the black tab is not at the end of its track, wind the large knob clockwise.

3 Verify Tubing & Needles



Verify that you are using the correct Precision tubing and High-Flo needle sets recommended by your healthcare provider and prescribed by your doctor.

6 Insert Syringe



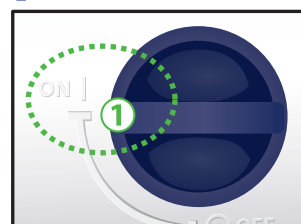
- With syringe gradations facing up, 1. load the syringe and its tubing into the syringe driver and 2. make sure the luer disc is fully seated in the driver's nose.

Prime Tubing:

Always follow your provider's protocol. Priming can be done by hand or by using the syringe driver.

If using the FREEDOM60 to prime:

7 Turn ON



1. Turn the ON/OFF switch to the ON position to prime (fill) the tubing.
2. Try to stop the flow about 2" short of the needle(s).



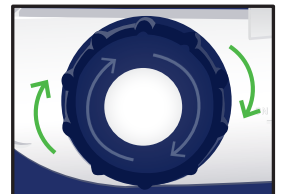
NOTE: It is recommended to insert the needle(s) dry to minimize site irritation.

8 Turn OFF



To stop flow to the needle(s), turn the ON/OFF switch to the OFF position.

9 Wind Back



Wind the large knob clockwise until the black tab is clearly not touching the syringe. This will release pressure on the plunger and stop the flow.

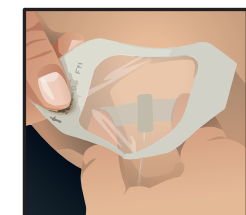
Insert Needles/Check for Blood Return:

10 Prepare Sites



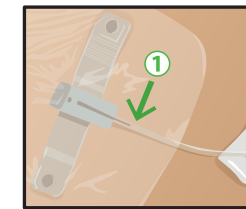
Select your site(s), cleanse with alcohol and let dry. Carefully remove shield from the needle tip, with care not to touch needle.

12 Secure

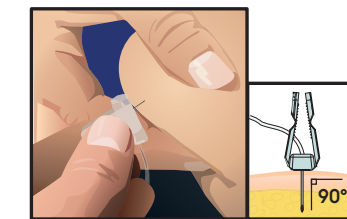


Secure needle(s) with adhesive dressing.

14 Watch



11 Insert



Pinch the skin and insert each needle into the subcutaneous tissue at a 90° angle.

13 Pull Back



Remove syringe from the FREEDOM60. Check for blood return by gently pulling back on the syringe plunger.

1. Watch to make sure no red/pink appears in tubing near your sites.
2. If blood return exists, clamp the flow to that site and call your healthcare provider to determine if the dose can be run using the remaining sites. If so, continue. If not, remove all needles, attach a new needle set and start again from step 6.

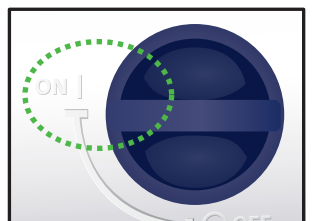
Begin Infusion:

15 Insert Syringe



With syringe gradations facing up, insert the syringe back into syringe driver.

16 Turn ON



Turn the ON/OFF switch to the ON position.

After Infusion is Complete:

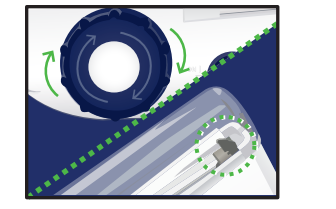
(When syringe is completely empty)

17 Turn OFF



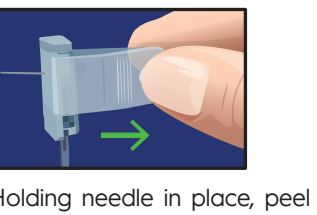
Once infusion is complete, turn the ON/OFF switch to the OFF position.

19 Wind Back



Wind the large knob until the black tab is at the end of its track.

18 Remove Needle(s)



Holding needle in place, peel back surrounding adhesive dressing. Remove needle(s) in a straight motion, opposite the direction you inserted it.

20 Remove Syringe



Remove the syringe, cleanse site(s), cover with bandage and discard of all sharps and biologics as required. Wipe down syringe driver if needed (see Q&A for cleaners).

Minimizing Site Reactions

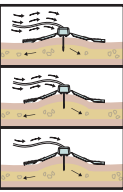
NOTE: Site reactions in new patients usually diminish over time as sub-q depots become more developed.

- Consider trying a longer needle
- Be sure needle is dry upon insertion
- Inquire about adding infusion sites
- Be aware of dressing/tape sensitivities
- Ask about trying a slower flow rate tubing



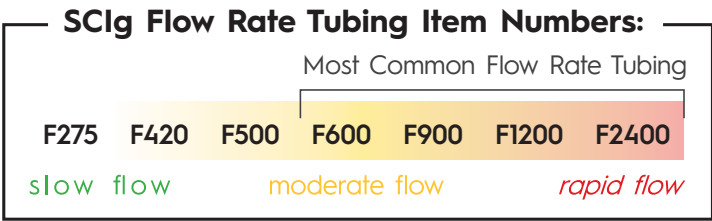
A Balanced Infusion Through DynEQ®

Did you know the FREEDOM60 is designed to slow down the infusion based on how well the patient's 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.



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 over 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.

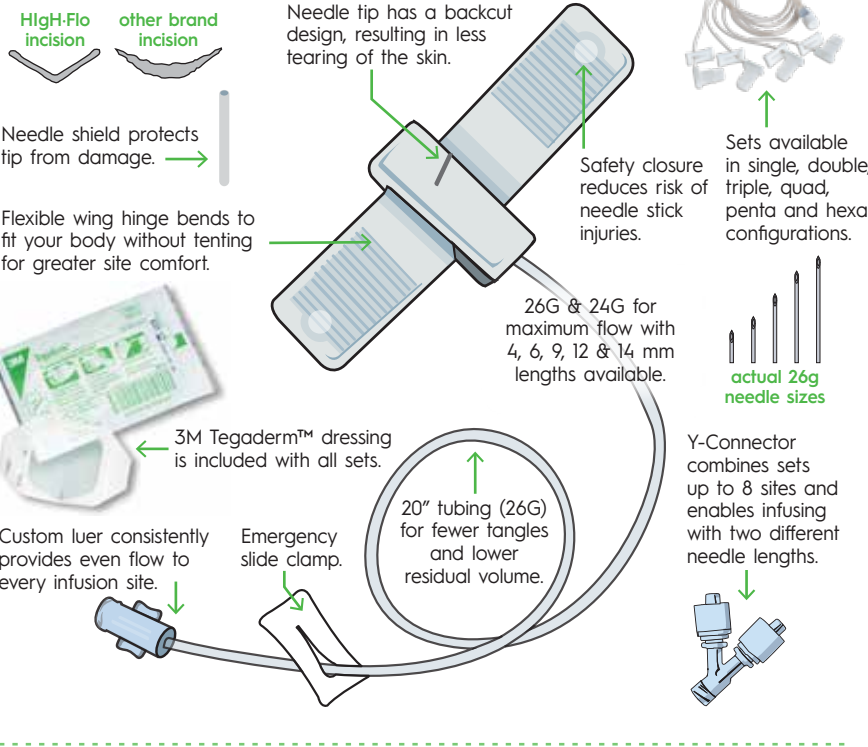
Don't forget your Precision!

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



HlGH-Flo Needles

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



HlGH-Flo needles provide dependable, equalized flow through every needle, helping to fill your infusion site(s) at the same rate - reducing pain, swelling and oozing.

Sub-q injection sites

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



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.

Troubleshooting

NOTE: For complete instructions, please refer to Instructions For Use included with your FREEDOM60.

Swelling, pain or redness at the site

- According to continuing research, needles may play a significant role in adverse site reactions. Among the many factors which may contribute to infusion site reactions are: the quality of needles being used; needle tip design; sharpness; length; number of sites; flow rate; and, dressing/covering.
- 1) Verify that you are using HlGH-Flo needle sets. If not, consult your provider to request them. For best results, use ONLY KORU Freedom infusion accessories.
 - 2) Be sure to insert your subcutaneous needles dry. IgG can irritate the skin.
 - 3) Assure that the needles you are using are long enough to reach your sub-q layers.
 - 4) Ask your provider about trying a slower rate tubing set, especially for your first few infusions.
 - 5) If you have been having difficulty with rotating sites, you may want to return to the sites that work best for you. Talk to your provider about options.

No flow

- 1) Assure that the syringe driver is in the ON position.
- 2) Make sure all slide clamps are unclamped. **NOTE:** if a slide clamp has been used/clamped, the tubing may be damaged. 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.
- 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 medication is absorbed through your tissue. If this is your first time with sub-q, it may take longer than expected because your body may need to create space in the subcutaneous layers in order to infuse in the time desired.
- 2) Avoid placing needles near areas of scar tissue or on top of muscle.
- 3) It is possible you may need more sites, longer needles or a faster flow rate tubing set.
- 4) Slow flow can also be a symptom of blocked or poor quality needles. If you are not using HlGH-Flo Subcutaneous Safety Needle Sets™, talk to your healthcare provider.

Flow continues for a short time even 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 drug return.

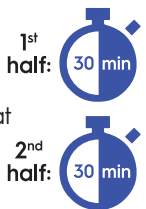
FREEDOM60® Q & A

- Q. Is my FREEDOM60 working? How can I tell if I am infusing?**

A. First, verify that your Precision tubing is the correct F-number. Then, check that the pump winds properly and makes a distinctive 'whirr' noise when turned on - this means it is working properly. Finally, note the time the infusion starts and watch that the syringe plunger moves in accordance with your estimated infusion time. If there is any doubt, please talk 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.
- Q. What's the noise the syringe driver creates when I first turn it on?**

A. That is the black tab looking for the syringe. Once the black tab finds the syringe, it will make a "thunk" sound and is then silent for the rest of the administration.



- Q. How do I administer a larger or smaller amount of fluid 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. What if I want my infusion to go faster?**

A. See the section above on the Precision Flow Rate Tubing set choices available. You may also consider adding an infusion site. Talk with your provider to see if a change is appropriate.
- 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 wind-up 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. Can the FREEDOM60 be used at high altitudes, such as on aircraft?**

A. Yes. It can be used in any position, at any altitude.
- Q. Can the FREEDOM60 be used for applications other than SCIg?**

A. Yes. The FREEDOM60 can be used to administer most intravenous and subcutaneous medications that will fit in a BD® 50 ml syringe.
- 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 pump's robust 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 about a possible replacement.
- Q. How do I clean the FREEDOM60?**

A. Soap and water or any non-alcohol surface disinfectant can be used. If it becomes necessary to clean the syringe shield, use a bottle brush. Be sure that no fluid enters inside of the syringe driver. See manual for more information.

Precision Tubing Q & A

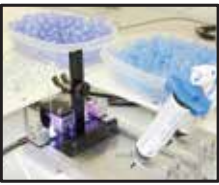
- Q. What makes Precision tubing so special?**

A. Precision Flow Rate Tubing™ is made in the USA. Our manufacturing expertise, mastered through years of experience, ensures accurate and dependable infusions when used with Freedom syringe drivers, maximizing the benefits Dynamic Equilibrium.
- 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. Immunoglobulin, for example, will flow much slower than an antibiotic. Since temperature also affects the viscosity of fluid, when temperature is cold, the flow slows down; when temperature is warm, the flow rate increases.
- 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.



HlGH-Flo Needles Q & A

- Q. Why are they called "HlGH-Flo"?**

A. Made for sub-q, 26 and 24 gauge HlGH-Flo (high performance flow) sets offer faster infusion rates than typical 27 gauge needle sets.

NOTE: If you are transitioning from 27 gauge, your provider might give you a different F-numbered Precision tubing set to keep your infusion time similar.
- Q. Why are they called HlGH-Flo "safety" needle sets?**

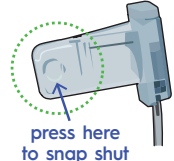
A. The butterfly wings 'snap shut' at the ends, to cover the needle after use. This feature is designed to help prevent accidental needle-stick injuries.
- Q. How can the smaller 26 gauge HlGH-Flo sets flow at the same rate as other brand sets using larger 24 gauge needles?**

A. HlGH-Flo needle sets are carefully designed to optimize fluid flow for the most efficient handling of drugs. This efficiency translates into higher flowrates from smaller diameter needles.
- Q. What is the least painful way to insert HlGH-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. You may notice that the HlGH-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. You can also talk to your provider about premedication.
- Q. I have heard HlGH-Flo can improve how my sites fill. How so?**

A. HlGH-Flo needles are carefully designed and thoroughly tested to ensure equal flow to every needle. To our knowledge, no other manufacturer goes through these steps. Variations in flow rate may be due to: the quality of other sets, placement of the needle (e.g., in scar tissue, or over muscle), needle length or new site location.
- Q. I heard I should insert the needles dry. What is the reason for this?**

A. Patients have found that inserting needles wet with drug can be irritating to the skin, so inserting dry allows the needles to penetrate into the subcutaneous layer without impacting the mast cells. This may result in less pain. If any medication ends up on the needle tip, do not touch the needle. Allow the needle to dry for a few minutes before insertion.



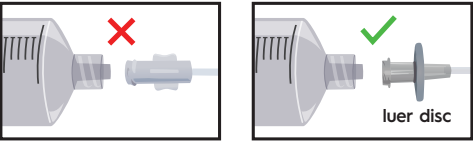
- To stop flow:**
- 1) Turn the switch OFF and wind the knob clockwise so the black tab moves away from the syringe releasing pressure on the plunger; or,
 - 2) Use the slide clamp. (We recommend using the slide clamp ONLY in the case of an emergency. Use of slide clamp can damage the tubing.)

Leakage at the site

- Continuing studies show that there are several factors to consider when overcoming drug leakage. These include: 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 provider about trying a longer needle.
 - 2) It is important that the site(s) you choose have a good amount of sub-q tissue. Ask your 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 provider about your options.
 - 4) Make sure you are using the site dressing included with the needle set.

Syringe will not load or remove from the syringe driver
You should not need to use significant force to load or 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) Make sure you have not attached the HlGH-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.



NOTE: Your FREEDOM60® is designed to slow down if it encounters a problem. If the syringe driver is making its distinctive 'whirr' and 'thunk' at the beginning of your infusion, it is working properly.

- Q. How do I know if I am using the correct length needle?**

A. Needle length should be determined according to how much sub-q tissue a patient has. 9 mm and 12 mm needles tend to work well with average sized patients; while 6 mm needles may be needed for very thin adults and children. Similarly, larger patients may require 14 mm needles.
- Q. When using more than one needle, do I need to do anything special to be sure the drug is evenly distributed?**

A. No special actions are necessary. Equal flow to each site reduces the risk that one site will over-fill. Dynamic Equilibrium automatically slows down the infusion to any site if pressure increases - to help prevent pain, swelling, and oozing. Sites that regularly fill more than others may be an indication that those subcutaneous layers have more space, or that different locations require different length needles.
- 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. HlGH-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.

