

Your home care provider is:

Drug _____

Dose (ml's) _____

Precision tubing set _____

High-Flo needle set _____

RMS resources (web links are case sensitive):



Like us on **facebook**
bit.ly/freedom60



Top 10 FAQs
bit.ly/topFAQs



Connections Blog Featuring Joanna Tierno
blog.rmsmedicalproducts.com



Interactive Patient Information Guide
joom.ag/xffb



6-minute Administration Training Video
bit.ly/adminvid2

RMS Medical Products has not performed any clinical testing to support the claims contained in this brochure. Claims have been taken from wide variety of reference materials including, but not limited to the following references:

- CSL Behring: Hizentra Package Insert
- Berger, M., Duff, K., Poll, J., Roy, S., "IgG Replacement by the Subcutaneous Route Using Preparations Licensed in the USA for Administration by Other Routes", 5th International Symposium on IVIG; 25-27, September 2003: Interlaken, Switzerland.
- Michael F Haller, "Converting Intravenous Dosing to Subcutaneous Dosing with Recombinant Human Hyaluronidase" MagCloud October 2, 2007. 1-11
- Gregory I Frost, "Recombinant human hyaluronidase (rHuPH20): an enabling platform for subcutaneous drug and fluid administration." Informa UK lit ISSN 1742-5247
- Viral Kamsara; Amitava Mitra; Yunhui Wu, "Subcutaneous Delivery" Drug Delivery Technology June 2009 Vol 9 No 5 pp 38:43
- Jorgensen, J.; Romsing, J.; Rasmussen, M.; Moller-Sonnergaard, J.; Vang, L.; Musaeus, L. "Pain Assessment of Subcutaneous Injections" The Annals of Pharmacotherapy 1996 July August, Vol 30 729-732

The information and suggestions contained herein are supplemental and limited, and as such are provided only for your convenience to assist you in the use of the FREEDOM60® with IgG. Always consult your physician and/or your home care provider for any medical advice, current approved protocols and refer to the package insert that comes with your drug. This brochure should not be used to make any medical decisions or to supercede instructions from your medical professionals.

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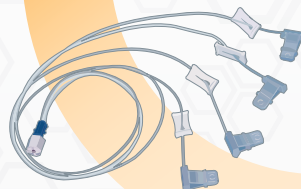
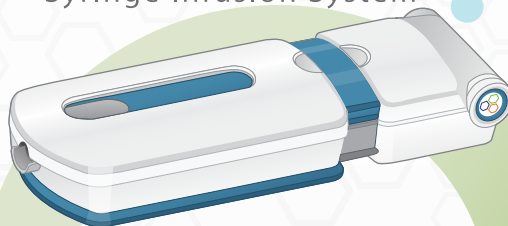
RMS™
Home Infusion
by RMS Medical Products

bit.ly/adminvid2

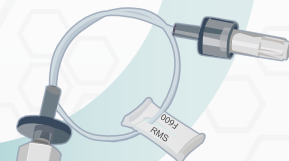
6-minute
training
video



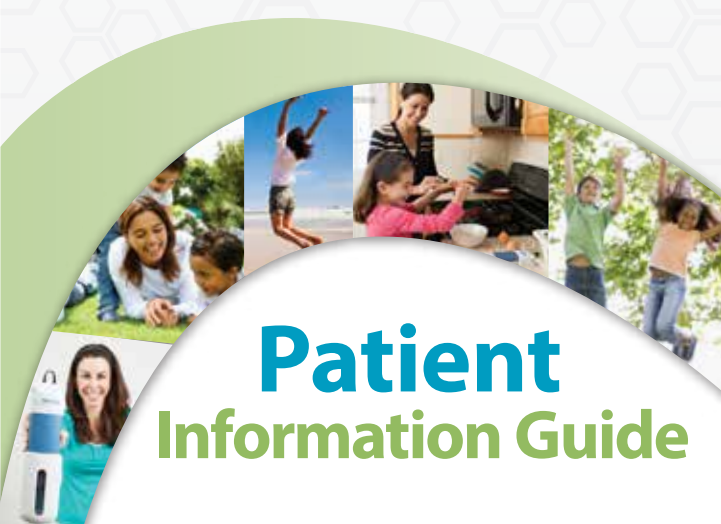
FreedomEdge™ Syringe Infusion System



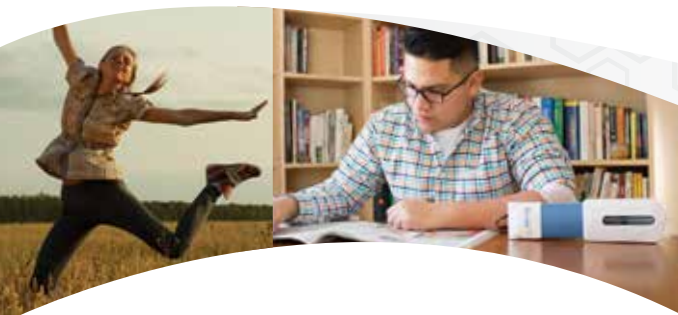
High-Flo™
Subcutaneous Safety Needle Sets



precision™
FLOW RATE TUBING™

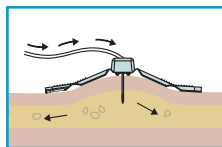


Patient Information Guide



Why Sub-q?

A subcutaneous (sub-q) infusion delivers medication through a thin needle to the fatty tissue just under the skin. See page 11 for common places to infuse.



Compared to IV, sub-q means smaller needles and more personal choice over when to infuse. It eliminates the need for vein punctures. Studies show sub-q may reduce adverse reactions such as severe headache, nausea, and vomiting. Many healthcare providers and patients prefer sub-q immunoglobulin (SCIg) over intravenous delivery (IVIg).

SCIg	vs.	IVIg
Can be administered daily to monthly, as determined by your provider		Administered once every 3-4 weeks
No venous access required		Venous access required
Can be self-infused at home after brief training		Usually administered by trained healthcare personnel
Can be done anywhere at patient's convenience		Usually administered at healthcare office/hospital

Subcutaneous slows down the rate that medication enters the bloodstream. Combined with more frequent delivery, this provides more consistent and stable blood levels, decreases side effects and improves overall quality of life.

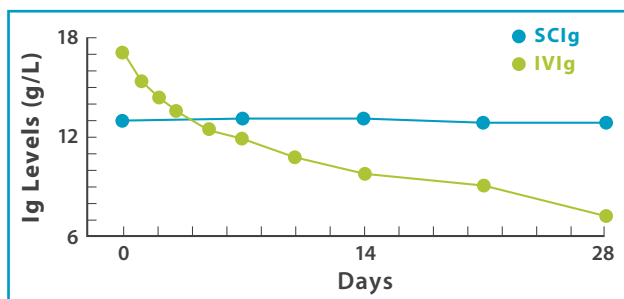


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For the interactive version of this Patient Information Guide, please visit: joom.ag/xffb

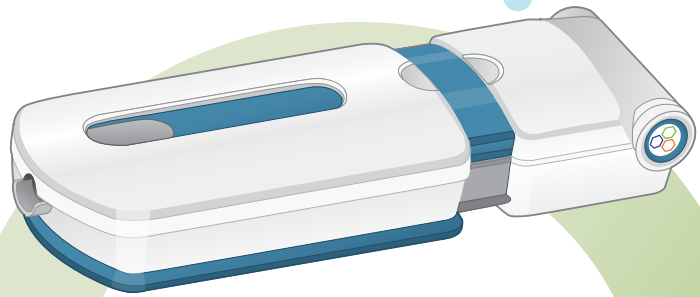
the system

Subcutaneous infusion you can rely on.

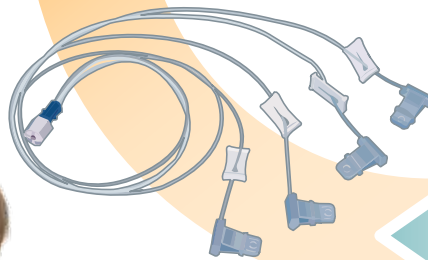
Thousands of patients depend on RMS' products. With RMS, and the support of your clinical team, you can succeed!



FreedomEdge™ *The freedom to infuse anywhere.*
Syringe Infusion System



connections matter



precision
FLOW RATE TUBING™

Delivering dependable and responsive infusions.

HighFlo™ *Designed for the sub-q patient's needs.*
Subcutaneous Safety Needle Sets

The Freedom infusion family:

For many years, the FREEDOM60® has been the pump people think of for sub-q.



Now, FreedomEdge™ offers all the technology of the FREEDOM60® in a more convenient shape for smaller syringes. It's easy to use, too. Simply load, close and go!

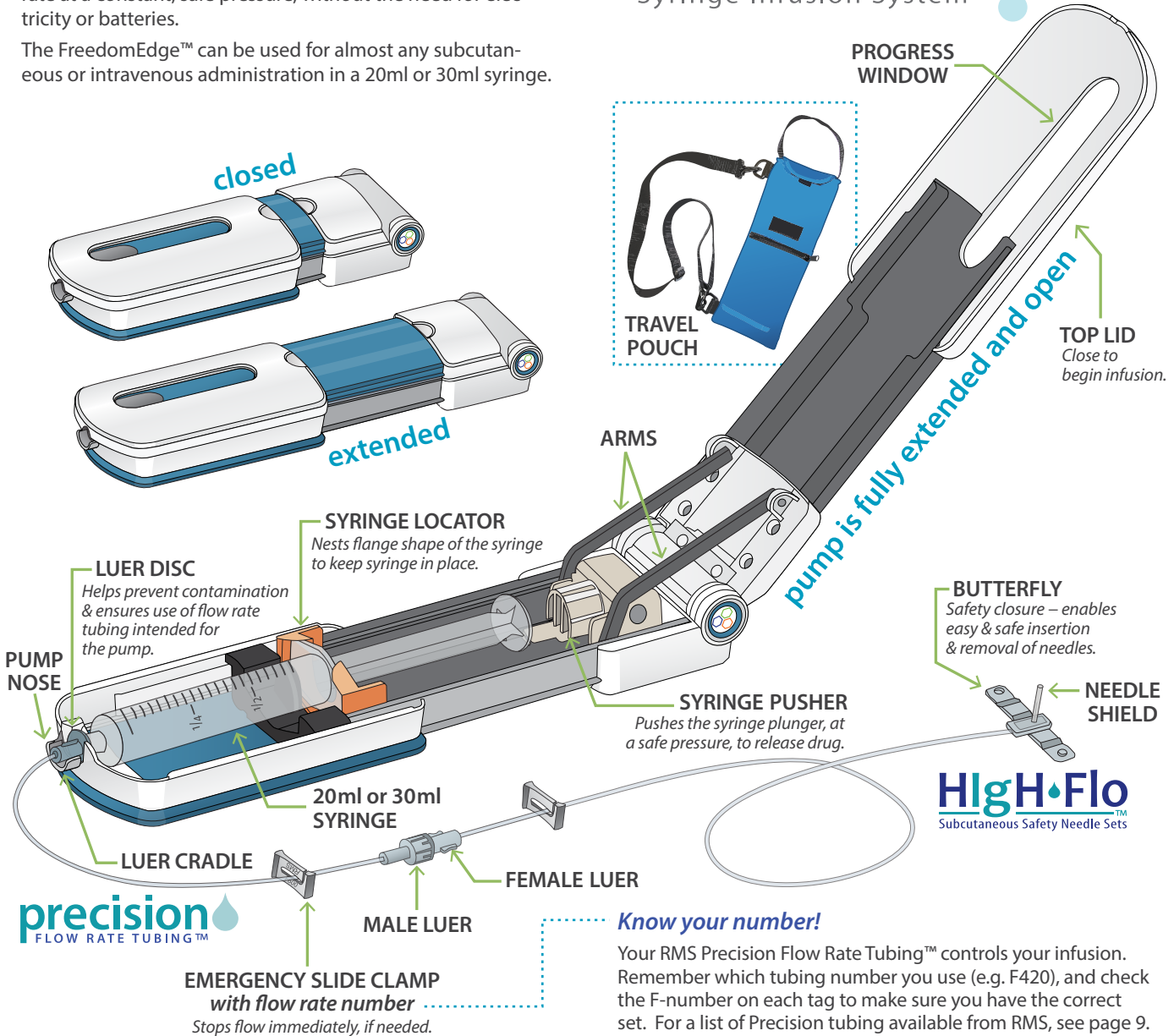
the pump

The FreedomEdge™ is a completely portable syringe infusion system that gives you the freedom to infuse anywhere.

A wide variety of tubing sets are available to control the flow rate at a constant, safe pressure, without the need for electricity or batteries.

The FreedomEdge™ can be used for almost any subcutaneous or intravenous administration in a 20ml or 30ml syringe.

FreedomEdge™ Syringe Infusion System



precision
FLOW RATE TUBING™

Minimizing Site Reactions

Can you minimize site reactions through your choice of supplies? Many patients say **yes!**

Things to keep in mind:

- Longer needles often help reduce site reactions;
- Go for more sites and less drug per site if you are still having problems;
- Inserting dry needles will minimize skin irritation;
- Watch out for dressing and tape sensitivities;
- Starting with a slower flow rate helps reduce initial local reactions (see tubing chart).



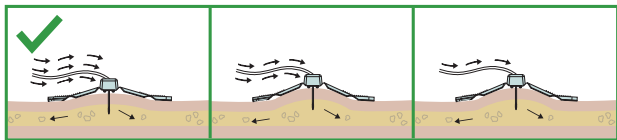
Note: Site reactions in new patients usually diminish over time as the sub-q depots become more developed.

For more details, see **Troubleshooting** on page 15.

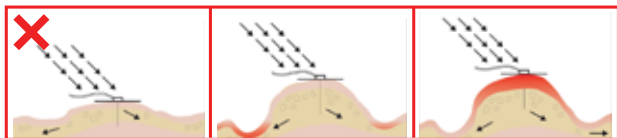
A Balanced Infusion Through DynEQ™

What does DynEQ™ mean for you?

DynEQ™ (Dynamic equilibrium) balances your fastest infusion with your most comfortable one. You get to infuse as rapidly as your provider recommends. If the pressure in your sites in- creases, the system immediately responds by auto- matically slowing down. The pump will maintain a safe pressure of 13.5 psi throughout the infusion (see below).



Other pumps, designed for constant flow (such as electronic pumps), respond to tissue saturation by increasing pumping pressure to maintain their programmed flow rate. High pump pressures can cause high pressures within infusion sites, leading to more problems at each site (shown below).



the tubing

precision FLOW RATE TUBING™



Change your infusion time with Precision

RMS Precision Flow Rate Tubing™ controls your flow rate and infusion time. It does this by creating a flow restriction, using some of the most accurate microbore tubing in the world. RMS makes quality our first priority, for predictable and consistent infusions.

Each F-number provides a different level of flow restriction, which, when combined with the viscosity of the medication, provides a precise delivery. The unique flow restriction of Precision combines with the constant safe pressure of the FreedomEdge™ to respond in real time to a patient's infusion sites with Dynamic Equilibrium.

Sub-q Flow Rate Tubing Item Numbers:

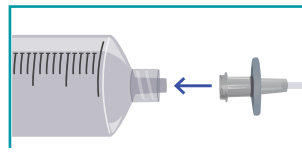
Most Common Sub-q Flow Rates						
F275	F420	F500	F600	F900	F1200	F2400
slow flow			moderate flow		rapid flow	

We offer more than twenty different varieties of Precision tubing, so that you can get the infusion rate you need. If you have been thinking about a change, ask your provider* to help determine which tubing is best for you.

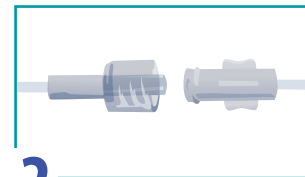
**This may be you immunologist, your specialty pharmacist, or another healthcare provider involved with your infusion supplies.*

For your safety, 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 FreedomEdge™ will eject the syringe.



1 connect tubing luer to syringe



2 connect tubing end to needles

HlgH-Flo™

Subcutaneous Safety Needle Sets

What goes into a great needle designed specifically for your sub-q?

Combined with FreedomEdge™, HlgH-Flo maximizes Dynamic Equilibrium for a fast, comfortable, and predictable infusion.

HlgH-Flo needle incision

other brand incision

Needle tip has a backcut design, which makes a tricuspid incision (shown above), resulting in less tearing of the skin.

Needle shield protects tip from damage.

3M Tegaderm™ dressing is included with all sets.

Emergency slide clamp.

Custom luer consistently provides even flow to every infusion site.

Y-Connector combines sets for more than 6 sites (up to 8), or to enable infusing with two different needle lengths.

26 gauge needle for maximum flow performance with 4, 6, 9, 12 & 14 mm lengths available.

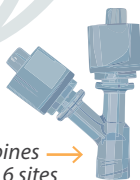
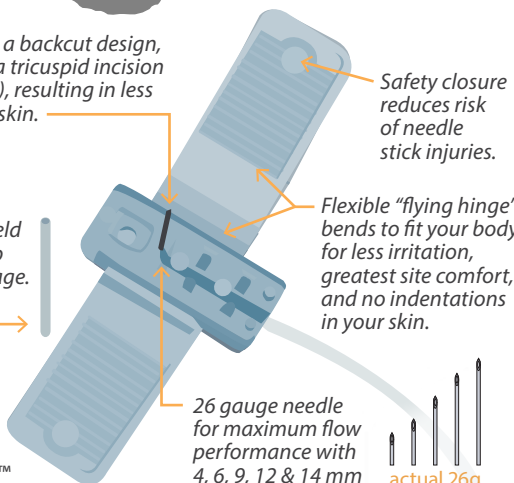
actual 26g needle sizes

20" tubing for fewer tangles and lower residual volume.

Sets available in single, double, triple, quad, penta and hexa configurations.

Safety closure reduces risk of needle stick injuries.

Flexible "flying hinge" bends to fit your body for less irritation, greatest site comfort, and no indentations in your skin.

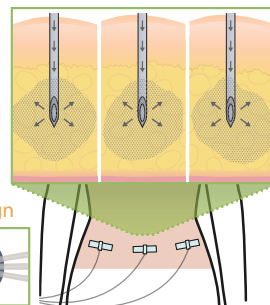


the needles

Avoid lumps & bumps

Get equalized flow to multiple sites with HlgH-Flo

Dependable flow, through every needle, helps your infusion sites all fill at the same rate – reducing pain, swelling and oozing.



“Each HlgH-Flo needle is sharp and goes in so smoothly. I also notice little or no irritation to each of my infusion sites.”

-Ted S.
SClg Patient

“As compared to the previous needles I was using, I experience significantly less discomfort when inserting the HlgH-Flo needle. In fact, I barely feel it at entry.”

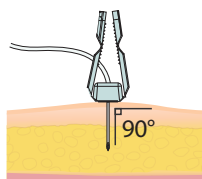
-Maureen H.
SClg Patient

Sub-q Injection Sites

Your healthcare provider can help find the best sites for your needle insertion. The abdomen is the most common place, but ask your provider about your options.

Some medications require that sites be 2+ inches apart, and that needles are inserted at a 90° angle. Check your package insert.

If and how to rotate infusion sites should be a subject for discussion with your healthcare provider. You may achieve better results by periodically returning to sites that have worked well in the past. However, some people find difficulty with repeated use of the same sites.



Sub-q Administration Instructions

Need help?

Contact your healthcare provider or call RMS at 1-800-624-9600.

Step 1 - prepare area/lay out supplies



Clean your work area with alcohol or disinfectant soap and water. Verify that you have the correct supplies, including the tubing set, needle set, and syringe size recommended by your healthcare provider, and lay them on a clean surface.

Step 2 - wash hands

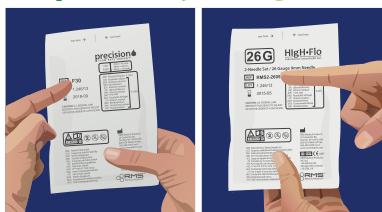
Wash hands thoroughly and, if required, put on disposable gloves.

Step 3 - fill syringe



Be sure the product is at room temperature before you begin filling the syringe with your required dose. Refer to the manufacturer's instructions, or ask your provider for more detailed filling instructions.

Step 4 - verify tubing and needles



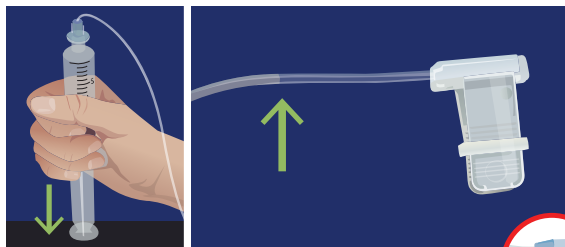
Again, verify that you are using the correct tubing and needles recommended by your healthcare provider and prescribed by your doctor.

Step 5 - attach syringe, tubing and needles



Remove sterile cap from the luer disc end of the Precision Flow Rate Tubing™ set and connect tubing to the syringe. Remove sterile caps from the ends of the High-Flo needle set and Precision tubing set. Connect the sets together, using care not to contaminate the ends.

Step 6 - priming needle set



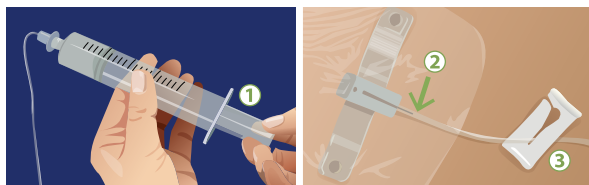
Grasp the syringe, and gently press down with steady pressure. Watch the tubing fill and stop flow about 2" short of the needles. **To minimize site irritation, it is recommended to insert needles dry.**

Step 7 - inserting needle(s)



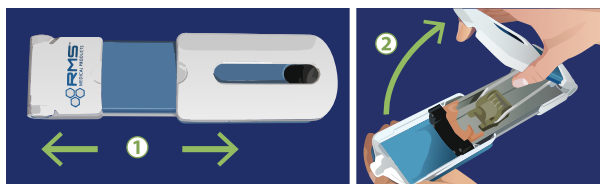
Select your sites, ① cleanse with alcohol and let dry. Carefully remove shield from the needle tip, without touching the needle. ② Pinch the skin and insert each needle into subcutaneous tissue. ③ Secure with adhesive dressing.

Step 8 - check for blood return



① Check for blood return by gently pulling back on the syringe plunger. ② **Watch to make sure no red or pink appears in the tubing near your sites.** If blood return does exist, ③ 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.

Step 9 - opening the pump



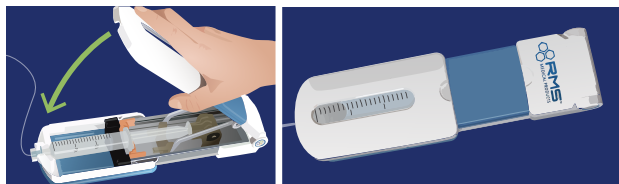
To open the pump, ① confirm FreedomEdge™ is fully extended. ② Then, open fully by lifting top cover.

Step 10 - loading the prepared syringe



① Load syringe into the pump, plunger end first. ② If needed, pull back on syringe locator to help ③ seat the luer disc into nose of the pump. *The syringe should sit in front of the locator.*

Step 11 - begin infusion

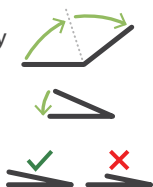


Start the infusion by closing the pump. The infusion will begin immediately.

Note: To pause the infusion at any time, simply open the pump.

To continue the infusion, re-close the top lid.

When closing the pump, make sure that the top lid is fully extended and aligns with the bottom portion of the pump.



Step 12 - upon completing infusion

Once the infusion is complete, open the pump and remove the syringe. One at a time, hold each needle in place and peel back any adhesive or dressing around it. Remove the needle in a straight motion, opposite the direction you inserted it. Remove needles from the syringe. Cleanse each site and cover with a bandage. Discard all sharps and biologics as required.

Troubleshooting

For complete step by step instructions, please refer to the Instructions For Use included with your pump.

Swelling, pain or redness at the site

Needles may play a significant role in adverse site reactions with sub-q according to continuing research. Among the many factors which may contribute to infusion site reactions are: the quality of the needles being used; design of needle tip; needle tip damage; sharpness; needle length; number of sites; flow rate; and, dressing/covering.

- 1) Verify you are using RMS HlgH-Flo needles. If not, consult your healthcare provider and inquire about trying HlgH-Flo.
- 2) Be sure to insert your subcutaneous needles dry. IgG tends to 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) Think about site location. If you have been having difficulty with rotating sites, you may want to return to the sites that work best for you. Talk with your provider about your options.

No flow

- 1) Make sure all slide clamps are unclamped. **Note:** if a slide clamp has been overused, or left clamped for an extended time, it can damage the tubing.
- 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 the tubing as it may be damaged.
- 3) With the pump empty, open and close the lid, watching that the syringe pusher slides freely and does not bind.

Slow flow

- 1) Confirm you are using the correct size syringe. 30ml syringes flow approximately 20% slower than 20ml syringes on the same Precision flow rate tubing.
- 2) 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

Patient Q&A

Slow Flow (continued)

in order to infuse in the time desired.

- 3) It is best to avoid placing needles near areas of scar tissue, or on top of muscle.
- 4) It is also possible you may need more sites, longer needles or a faster flow rate tubing set.
- 5) 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 about trying them.

Note: if a slide clamp has been overused, or left clamped for an extended time, it can damage the tubing.

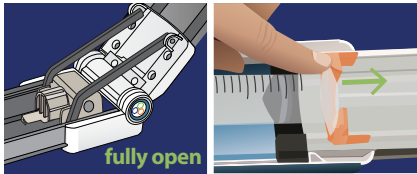
Cannot stop flow

- 1) The best way to immediately stop flow is to fully open the lid of the pump.
- 2) We recommend using the tubing set slide clamp only in case of an emergency.

Syringe will not load or remove from pump

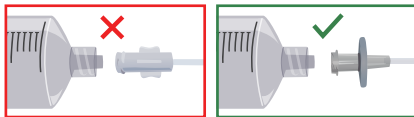
You will never need to use force to load or remove a syringe.

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



Syringe will not stay inside in the pump

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



- 2) Be sure you are using RMS Precision Flow Rate Tubing™ (with the luer disc).
- 3) Make sure that the luer disc at the end of the tubing is properly seated in the pump's nose (see image on page 6).

Note: Your FreedomEdge™ is designed to slow down if it encounters a problem. For more details about how the FreedomEdge™ works to protect you, see DynEQ™ on page 8.

Always consult your healthcare provider and refer to the product's Instructions For Use.

the pump FreedomEdge™

Q. How can I tell if the FreedomEdge™ is working and that I am receiving my infusion?

A. Write down the time the infusion started and verify that you are using the correct control rate tubing and syringe recommended by your healthcare provider. Then, watch that the syringe plunger moves in accordance with your infusion time. If you expect 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. 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 the two 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 just about equal, it usually means your sites are accepting the drug well, and the site pressure is not increasing over the duration of your infusion.



Q. What if I want to administer a larger or smaller amount of fluid?

A. If a dose is larger than 30ml, you can load an additional syringe using the same tubing and needle set. For smaller volumes, the pump system automatically adjusts to whatever amount is contained in the syringe. We also offer the FREEDOM60® pump, which has the same performance as FreedomEdge™, but for 60ml syringes.

Q. How do I clean the FreedomEdge™?

A. Refer to the Instructions For Use for information on how to clean the FreedomEdge™.

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

A. See page 9 to learn more about all the RMS Precision Flow Rate Tubing™ choices available. Then talk with your provider to see if a change is appropriate.

Q. Can the FreedomEdge™ be used at high altitudes, such as in aircraft?

A. Yes. It can be used in any position, at any altitude.

Q. Can the FreedomEdge™ be used for applications other than SCIG?

A. Yes. The FreedomEdge™ can be used to administer most intravenous and subcutaneous medication that will fit in a 20ml or 30ml syringe.

Q. Does the FreedomEdge™ need maintenance?

A. The FreedomEdge™ is designed to operate without scheduled maintenance. If you ever experience a pump problem, immediately advise your healthcare provider who can arrange for replacement if necessary.

Q. Do you offer a carrying bag for the pump?

A. Yes, RMS offers a travel pouch. If you would like a pouch, please contact the provider who sent you your pump.

the tubing precision™

Q. What makes Precision tubing so special?



A. RMS Precision Flow Rate Tubing™ is made in the USA at the RMS factory. Our manufacturing expertise, mastered through decades of experience, ensures accurate and dependable infusions with RMS Home Infusion pumps, maximizing the benefits of DynEQ™ (Dynamic Equilibrium).

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

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

Q. Is longer tubing available? Do you offer extension sets?

A. Yes, we offer an extension set called F-EXT. We designed our tubing and needles for the least possible residual volume, and to reduce the risk of catching loose tubing on things. F-EXT gives you a choice.

Q. What affects the flow rate of the FreedomEdge™?

A. The tubing and needles you use will affect your flow rate. Different brands of needles will flow differently. The viscosity (thickness) of the fluid also makes a big difference. Immunoglobulin, for example, will flow much slower than an antibiotic. Temperature also affects the viscosity of fluid, slowing flow down when cold, and speeding up when warm.

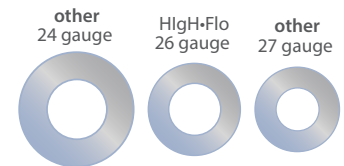
Q. What is the temperature range that I can infuse in?

A. For accuracy and safety, most medications must be delivered at room temperature.

the needles HlgH•Flo™

Q. Why do you call them HlgH•Flo?

A. HlgH•Flo needles are designed to provide flow rates as fast as you need. If you are transitioning from most 27 gauge needle sets, this could be much faster than you are used to. In this case, your healthcare provider may choose to provide you with the next lower "F-number", Precision tubing set, to maintain an infusion rate similar to your current one.



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 flow rates from smaller diameter needles.

Q. What is the least painful way to insert RMS HlgH-Flo Subcutaneous Safety Needles™?

A. Many patients tell us that they grab the wings above the needle, then pinch the skin at the selected infusion site as close together between their fingers as possible, and insert the needle with a dart-like motion into the pinched area. This seems to produce the least resistance to the needle sliding in.



You may notice that the HlgH-Flo butterfly wings are very flexible, making this procedure easy. Each site should be at least 2" apart and needles should be inserted at a 90° angle, as mentioned on page 11. You can also talk to your provider about premedication.

Q. I heard I should insert the needles dry. What is the reason for this?

A. Patients have found that inserting needles wet with immunoglobulin is irritating to the mast cells in 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 medication ends up on the needle tip, do not touch the needle. Allow the needle to dry for a few minutes before insertion.**



Q. Why is a 3M Tegaderm™ dressing supplied with each needle?

A. Consensus from several medical centers and many patients was that genuine 3M Tegaderm™ is preferred by

most patients, so we include it with your needles. We were told it had the least irritation and best adhesion to the skin. If you are a patient with dry or sensitive skin and find that the 3M Tegaderm™ is irritating, you may need to try different dressings, protective spray, paper tape, or a cloth wrap. Ask your healthcare provider for suggestions.



Q. I have heard HlgH-Flo can improve how my sites fill. How?

A. HlgH-Flo needles are carefully designed and thoroughly tested to ensure equal flow to every needle. To our knowledge, no other manufacturers' sets go through these steps. Varying flow rate may be due to: the manufacture of other sets, placement of the needle (e.g., in scar tissue, or over muscle), needle length or new site location.

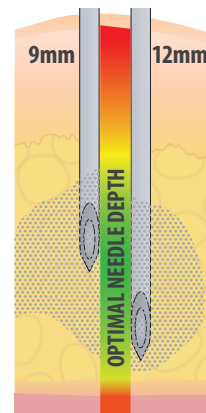
Q. Can HlgH-Flo be used with 20% solutions of IgG as well as 10% immunoglobulin?

A. Yes. HlgH-Flo needles are FDA-cleared for all sub-q medications. The 10% solutions will flow faster than 20%. Flow can be adjusted by changing the selection of Precision tubing. If your sites are capable, the needles will be able to deliver the highest flow rate as stated in the drug's package insert.

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. 9mm and 12mm needles tend to work well with average sized patients (as shown in the image to the right); while 6mm needles may be needed for very thin people and children. Similarly, larger patients may require 14mm needles.

When in doubt, or to address leaking and irritation, select the next longest needle and a slower flow rate for more positive outcomes.



Q. Why do you call HlgH-Flo “safety” needle sets?

A. The butterfly wings close at the ends, to encapsulate the needle after use. This feature of RMS HlgH-Flo Subcutaneous Safety Needle Sets is designed to help prevent accidental needlestick injuries.



Q. What could cause drug to leak at the infusion site?

A. Confirm you are using HlgH-Flo needles. Some possible causes include: excessive movement, a needle length that is too short, a site with too little subcutaneous tissue, too much volume in an individual site or over-saturation of the sites, due to too fast a flow rate.

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 still regularly fill more than others may be an indication that those subcutaneous layers have more space, or that different locations require different length needles.



custom luer design
(quad set)

Q. Can HlgH-Flo needles be used with other pumps besides the FreedomEdge™?

A. Yes. Our needles are compatible with other pumps, including RMS' FREEDOM60®. However, only RMS Home Infusion systems offer DynEQ™ (Dynamic Equilibrium), which automatically adjusts the flow rate if the tissues at the infusion site become saturated. To achieve the full benefits of DynEQ™, we recommend that you use HlgH-Flo needle sets with our pumps. Constant flow pumps use higher pressures and are not sensitive to the back pressure and, therefore, will continue the stated flow rate beyond

what might be comfortable. This may result in painful, red swollen lumps at the site, drug oozing out of the needles and site irritation.

Q. Can I check for blood return at the same time for all my sites, or do I have to clamp them each off individually?

A. Actually, we recommend you don't clamp your needles at all, except in the case of an emergency or at the end of your infusion. When checking for blood return, we suggest that you just draw back on the syringe and watch near **all** your sites for red or pink in the lines, but follow your provider's protocols.

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. We have provided a closure mechanism in the wings of the butterfly to cover the needle and minimize chances of a needlestick injury. Simply press 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.

Q. Where can I get the FreedomEdge™, Precision tubing and HlgH-Flo needles? What if I have more questions?

A. Ask your healthcare provider. Feel free to call/email us for more information at 1-800-624-9600 (toll free), 1-845-469-2042 (local), or info@rmsmedicalproducts.com.

Also, feel free to ask about the FREEDOM60® Syringe Infusion System, for 60ml syringe infusions.

